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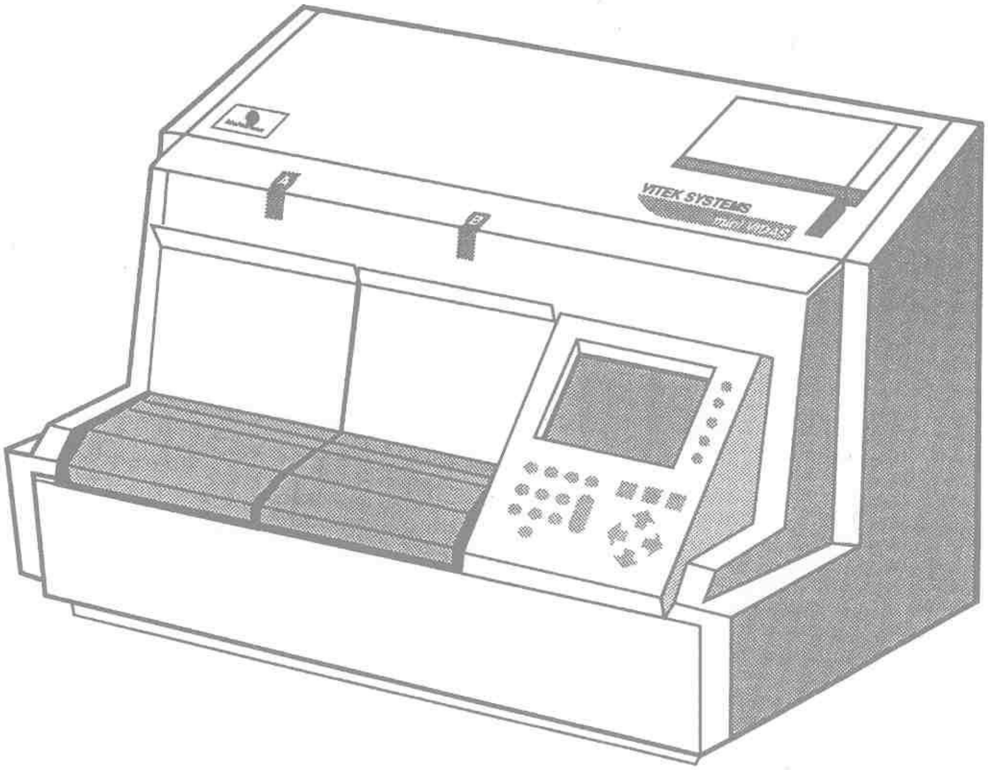
VITEK SYSTEMS
mini VIDAS
A
B

# mini VIDAS
# Operator's Manual

bioMérieux Vitek, Inc.

bioMérieux

# mini VIDAS
# Operators's Manual

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REV 0295

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This publication is based on mini VIDAS software version VICVID-R2.15.

Updates are made periodically to this document. Software revisions and other changes will be included in subsequent versions.

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Seller, bioMérieux Vitek, Inc., warrants the mini VIDAS instrument to the original purchaser for a period of one (1) year after date of acceptance against defects in material and workmanship and defects arising from failure to conform to specifications applicable on the date of installation. Seller further agrees to correct, either by repair, or, at its election, by replacement, any such defect found on examination to have occurred, under normal use and service, during such one (1) year period, provided Seller is promptly notified in writing upon discovery of such defect. The total mini VIDAS instrument, including all of its system elements, are warranted to be new or equivalent to new for the full product warranty period of one year. Disposables and replacement items, with a normal life expectancy of less than one (1) year, such as batteries, lamps, and bulbs, are excluded from this Warranty.

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This Warranty shall not be extended or altered except by written instrument signed by Seller.

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# 1. How To Use This Manual

## Introduction

The mini VIDAS Operator's Manual is a complete guide for the system. It includes the information you need to install and set up the instrument, operate the hardware and software portions of the system, obtain and interpret reports, and identify and correct some of the errors that may occur.

As you become more familiar with the easy-to-use procedures of the mini VIDAS, you will find that this manual becomes more a reference than a companion guide. It has, however, been organized to both guide new users through their first experiences with the system, and also to serve the more experienced users who may need occasional help.

## Organization of the Manual

The information in the manual is organized among seven chapters. They are arranged so that the information you need first is in the beginning of the manual. Information required after the system is operating and producing results is found in later chapters. Following is a brief outline of what you will find:

- Chapter 2 Setting Up Your System. This chapter is a complete guide for the installation and setup of the mini VIDAS. It begins with the unboxing of the instrument and proceeds through its power up and configuration.
- Chapter 3 Parts of the System. Use this chapter to familiarize yourself with the mini VIDAS hardware, and the basic parts of the software system. This chapter describes the Reagent Strips and other parts of the assay kits you use with the system.
- Chapter 4 Routine Procedures. This is the main chapter for the operation of the system. It contains the procedures that you will use most often, concentrating mainly on running assays.
- Chapter 5 Results and Reports. This chapter contains primarily reference material. It describes the analysis methods used by the mini VIDAS to obtain results. The chapter also describes in detail the assay reports the system generates automatically after a run.
- Chapter 6 Miscellaneous Operations. This chapter contains several different types of procedures, including changing some of the factoring settings and testing parts of the hardware. It describes useful operations that you may use only occasionally.
- Chapter 7 Error Handling. The mini VIDAS has a system for detecting and reporting errors. This chapter describes the error reporting system, the error messages you may see, and how to respond to correctable error conditions.

Following these chapters are appendices listing environmental, space, and electrical requirements; maintenance procedures including decontamination and routine cleaning; and procedures for installing optional external hardware. You will also find a glossary of terms and an index in the back of the manual.

## Typographic Conventions

Following are the terms and visual cues used in this manual to aid in your understanding of the procedures.

### The mini VIDAS Keypad

There are 24 keys on the mini VIDAS keypad. They are divided among four groups, according to their function:

- Number keys. A standard set of digits, as you would find on a calculator.

  In referring to these keys, we use their general name enclosed in angle brackets: <Number Key>.

- Function keys. Three keys with specially programmed functions.

  In procedures, these keys are referred to by their individual names, enclosed in angle brackets. For example

  > Press <Previous Screen> to return to the menu.

  ★ Detailed descriptions of these function keys are in Chapter 3.

- Arrow keys. Four keys used to move the cursor on some screens.

  The arrow keys are referenced by their direction, enclosed in angle brackets: <UP>, <DOWN>, <LEFT>, and <RIGHT>.

- Selection keys. Five keys used to select options from the screen.

  The selection keys are used most often in the operation of the system. The manual therefore uses special conventions for them.

  - An operation involving a selection key always begins with "Select." Contrast this with the other keys, where we use the word "press."
  - The use of a selection key is always associated with a selection option displayed on the screen. The name of the option appears inside braces.

    A selection reference specifically by name appears inside braces and in bold type. For example

    > Select `[Utility Menu]` on the Main Menu.

    A selection referenced as a general category appears inside braces but in normal type. For example

    > Select one of the [sections] to halt.

# 2. Setting Up Your System

## Introduction

This chapter covers the very first steps you need to take before you can use the mini VIDAS. Procedures found in this chapter are

- Unpacking the mini VIDAS 2-2
  - Preparations Before Unpacking 2-2
  - Unpacking 2-2
- Starting the System 2-3
- Configuring the mini VIDAS 2-6
  - Dose Units 2-7
  - User ID 2-8
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  - Backing Up Your Configuration Settings 2-26
- Installing Paper in the Printer 2-26

## Unpacking the mini VIDAS

### Preparations Before Unpacking

The only thing you need do in preparing to unpack your mini VIDAS is to prepare a suitable benchtop space for it. In doing so, remember the following:

- The mini VIDAS is 21 ¼ inches (54 cm) wide, 17 ¼ inches (44 cm) high, and 21 inches (53 cm) deep.
- There must be at least 2 inches (5 cm) of clearance on each side and on the top, and 4 inches (10 cm) behind.
- You must be able to reach behind the system to access the power, cable connections, and memory card slot.
- The front of the system must be totally clear of any obstructions.
- The system must be placed close enough to an adequate power supply so that the power cord (included) can reach the outlet.
- The ambient temperature in the mini VIDAS's location must be 15° - 30°C. The system should therefore be kept away from air vents, direct sunlight, or other objects that could affect temperature performance.
- The bench must be level within 5°.

★ See Appendix A for a complete listing of mini VIDAS specifications.

### Unpacking the mini VIDAS

Step 1 Place the box containing the mini VIDAS on the floor and open the top of the carton.

**NOTE:** Retain the shipping carton and packing materials in case you need to ship the mini VIDAS at a later date.

Step 2

Remove the instrument from the carton and place it on the floor.

**CAUTION**

The mini VIDAS weighs 84 lb (38.18 kg). Two people should be used to remove it from its carton and to lift it to the benchtop.

Step 3

Remove the foam end caps and the antistatic bag. (See Note above.)

Step 4

Place the instrument on the benchtop.

Step 5

Remove the tape securing the dust covers. (See the figure below.)

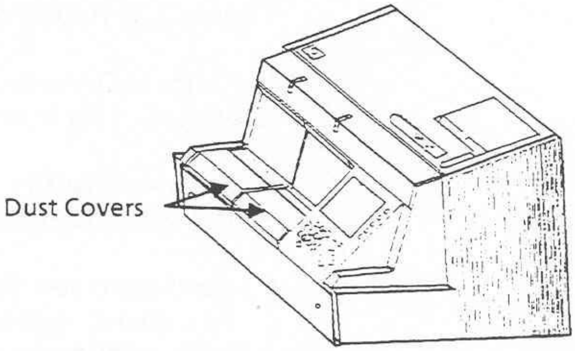


Figure 2–1 mini VIDAS Dust Covers

Step 6

Open each dust cover and remove the shipping block. (See Note in Step 1 above.)

**NOTE:** The shipping block in Section A (on the left as you face the instrument) has a rod attached to it. This rod secures the optical scan head during shipment and must be removed with the shipping block.

## Starting the mini VIDAS

**NOTE:** All software required for the system has been loaded into the mini VIDAS. Follow these steps to start your system.

Step 1

Connect the power cord to the mini VIDAS and an appropriate power outlet.

★ See Appendix A for mini VIDAS power specifications.

Step 2

Reach behind the instrument and turn the power on. (See figure below.)

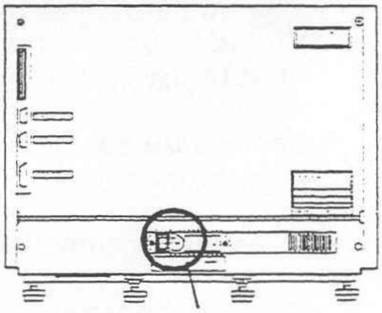
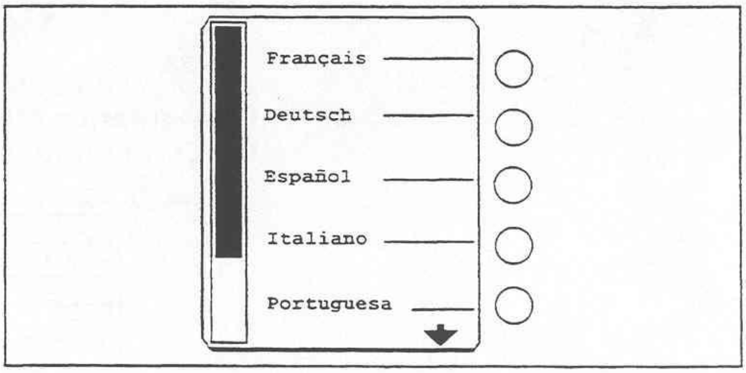


Figure 2–2 Power Switch

The mini VIDAS now goes through its power up sequence. This involves the following:

- Software self test and diagnostics. This part of the sequence is not noticeable.
- Hardware self test. The mini VIDAS exercises all its motors. Expect to hear noises inside the instrument and to see the Reagent Strip trays (under the dust covers) retract into the instrument.
- Software boot sequence. The boot sequence is a program that loads the mini VIDAS software into its memory. During this sequence, expect to see the following messages on the display screen:
    - VIC Boot R1.0
    - Booting
    - Initializing... Please Wait

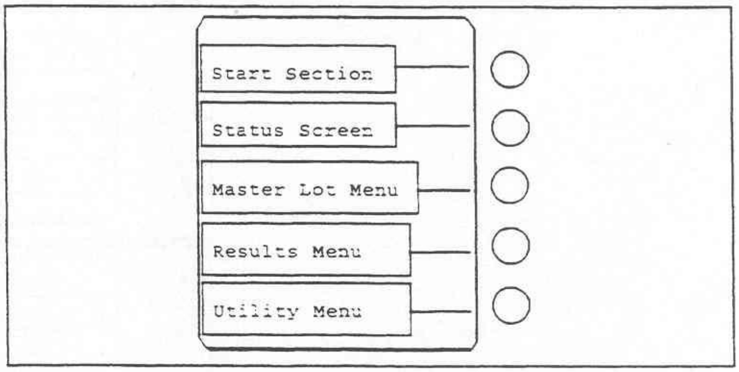
The first time that power is applied to your mini-VIDAS, the language selection screen appears:


Français
Deutsch
Español
Italiano
Portuguesa

Step 3 Press the <DOWN> or <UP> arrow keys, as needed, until the language you want appears on the screen.

Step 4 Select the language you want to use.

This completes the initial startup sequence and brings up the mini VIDAS Main Menu:


Start Section
Status Screen
Master Lot Menu
Results Menu
Utility Menu

## Configuring the mini VIDAS

The procedures in this section are accessed from the Configuration Menu. Proceed as follows to reach the Configuration Menu.

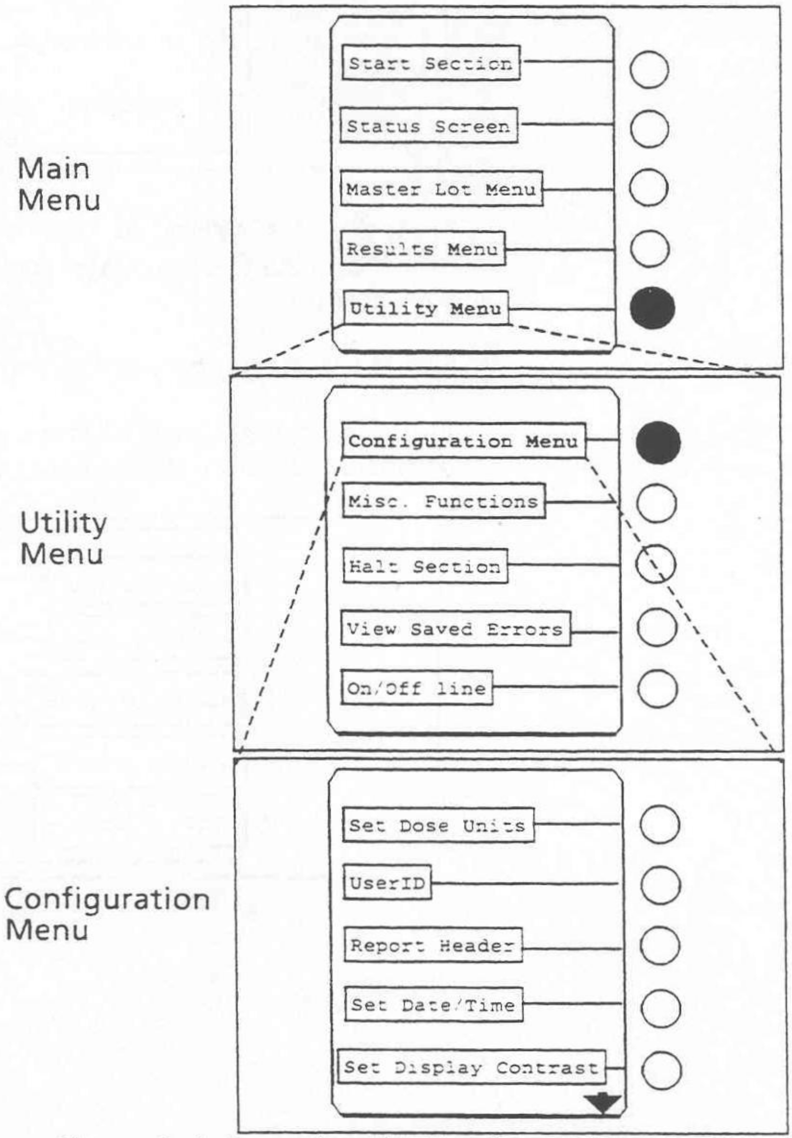

Main Menu
Start Section ○
Status Screen ○
Master Lot Menu ○
Results Menu ○
Utility Menu ●
Utility Menu
Configuration Menu ●
Misc. Functions ○
Halt Section ○
View Saved Errors ○
On/Off line ○
Configuration Menu
Set Dose Units ○
UserID ○
Report Header ○
Set Date/Time ○
Set Display Contrast ○

Figure 2–1 Accessing the Configuration Menu

## Setting Dose Units

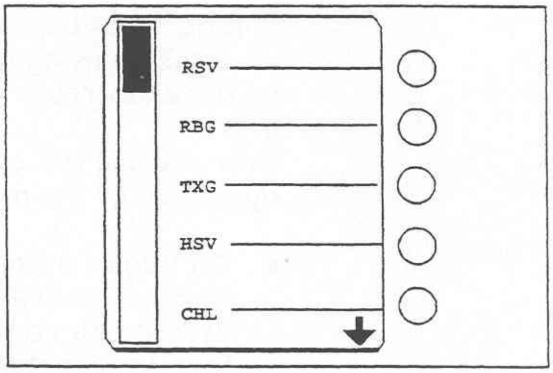
This option is used to set the standard units to be applied to results for the quantitative mini VIDAS assays.

Step 1

Select `[Set Dose Units]` on the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

An assay selection list, similar to the following*, appears:



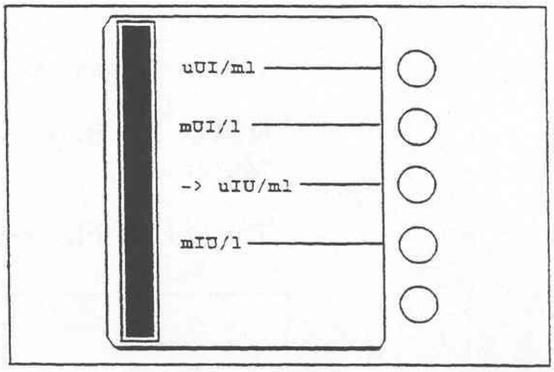
Step 2

Optional. Press the <DOWN> or <UP> arrow keys, as needed, until the assay you want appears on the screen.

Step 3

Select [an assay] whose dose units you want to set.

A screen similar to the following appears:



Note that the dose unit currently set is indicated by an arrow.

---

* The assays that actually appear may be limited by the `[Show All Assays]` configuration option, shown later in this chapter.

Step 4

Select the [dose unit] desired for this assay.

The display returns to the Configuration Menu.

Step 5

Step 5 has two options:

- Select another assay to set the dose units.

  Repeat Steps 2 - 4.

- Press the <Previous Screen> key to return to the Configuration Menu.

## Setting User ID

This option is used to enter an ID for the people who will be using the mini VIDAS. These IDs appear on the assay report.

How you use this configuration option affects the operation of the mini VIDAS in the following ways:

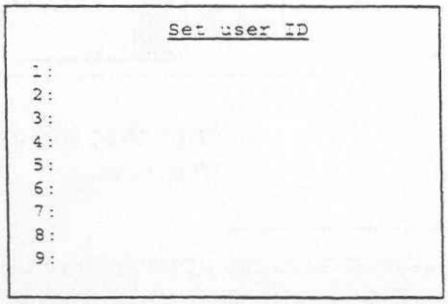
- Set two or more (up to nine) user IDs. When you start assays in a Section, you are asked to select a user ID from the group you create here. If both Sections are started together, one user is identified. If the Sections are started separately, two users can be identified.
- Set one user ID. That user is automatically identified on all reports.
- Set no user ID. You are not prompted for a user ID, and the user field is left blank on the reports.

Step 1

Select `[User ID]` on the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

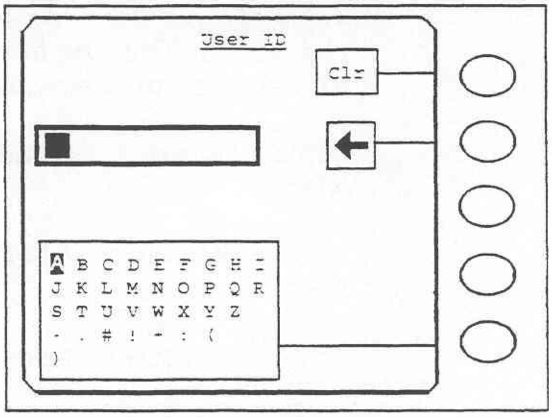
The Set User ID screen appears:



```
              Set user ID

1:
2:
3:
4:
5:
6:
7:
8:
9:
```

Step 2

Press a digit, 1 - 9, on the <Number Key> pad, corresponding to the first through the ninth user entered. The User ID screen appears:



The space next to the "Z" character can be used to create a space in your ID.

Step 3

Press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box.

Step 4

Select the [character box].

The character appears in the cursor box.

Step 5

Repeat Steps 3 and 4 to create an ID of up to 10 characters.

Use these functions as required:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor

Step 6

Press <Previous Screen> to return to the Set ID screen.

Step 7

Step 7 has two options:

- Repeat Steps 2 - 6 to enter another user.
- Press the <Previous Screen> key to return to the Configuration Menu.

## Setting the Report Header

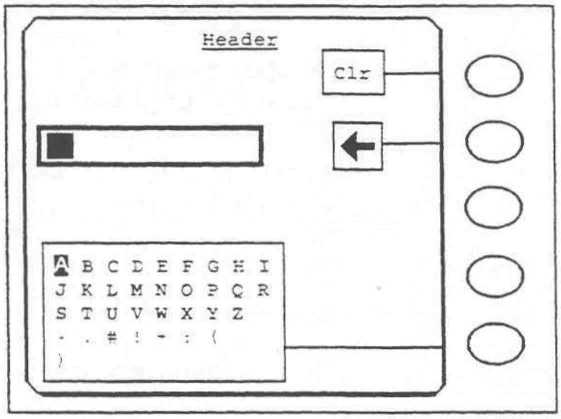
This option is used to define a line of up to 32 characters. This line appears in the header information of the assay report.

Step 1

Select `[Report Header]` on the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

The Header screen appears:



The space next to the "Z" character can be used to create a space in your header.

Step 2

Press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box.

Step 3

Press the [selection key] for the character box to select the character, which then appears in the cursor box.

Step 4

Repeat Steps 2 and 3 to create a report header of up to 32 characters.

Alternately, use these functions:

- `[Clr]` to clear the box containing the cursor
- `[←]` to delete one character in front of the cursor

**NOTE:** The display shows a maximum of 14 characters. If you create a larger header, the other characters scroll off the display to the left; this is indicated by the symbol "<."

Step 5

Press the <Previous Screen> key to return to the Configuration Menu.

## Setting the Date and Time

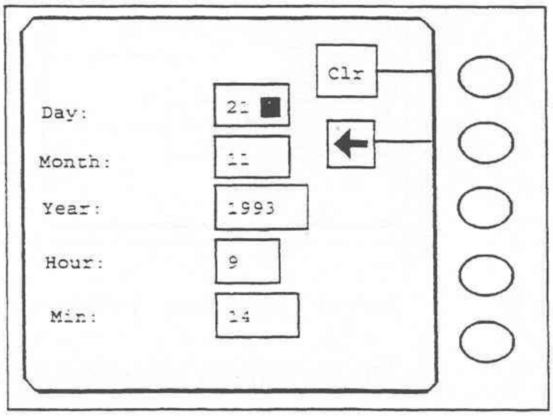
This option is used to set the date and time for the mini VIDAS system. These values appear on the assay report and all other places in the system where the date or time of day is used.

Step 1

Select `[Set Date/Time]` on the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

The following screen appears:



Day: 21

Month: 11

Year: 1993

Hour: 9

Min: 14

Step 2

Set the date and time using the following functions:

- `[Clr]` to clear the box containing the cursor
- `[←]` to delete one character in front of the cursor
- <Number Key> pad to fill in the numerical value for a day, month, year, hour, or minute.

  **NOTE:** Use the <ENTER> key to move the cursor to the next box.

Step 3

Press the <Previous Screen> key to return to the Configuration Menu.

## Selecting the Printer

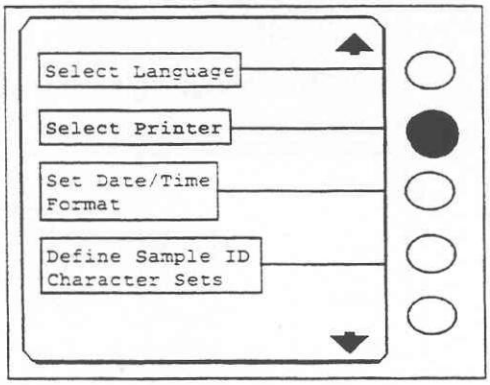
With this option you can select the internal thermal printer, or an external Epson-compatible printer. The internal printer is the default.

Step 1

Press the <DOWN> arrow key on the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

The second page of the Configuration Menu appears:



Step 2

Select `[Select Printer]`.

The following selection appears:

- `[Internal Printer]`
- `[External Printer]`

**NOTE:** A ☒ symbol indicates the current setting.

Step 3

Select the printer you want to use.

**IMPORTANT:**

Before selecting an external printer, see Appendix C for external printer installation instructions.

Step 4

Press the <Previous Screen> key to return to the Configuration Menu.

## Setting the Date/Time Format

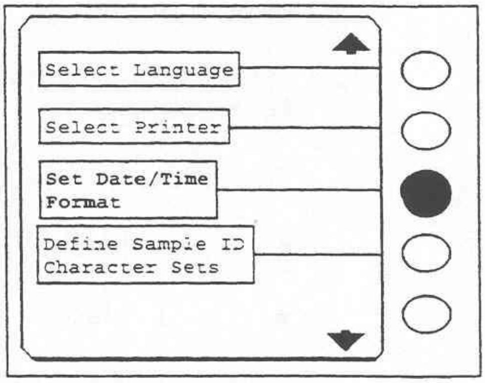
Use this option to set the format of the date and time used on the reports. This option also allows you to select the separators (colons, periods, or commas) you want to use in the format.

Step 1

Press the <DOWN> arrow key from the first page of the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

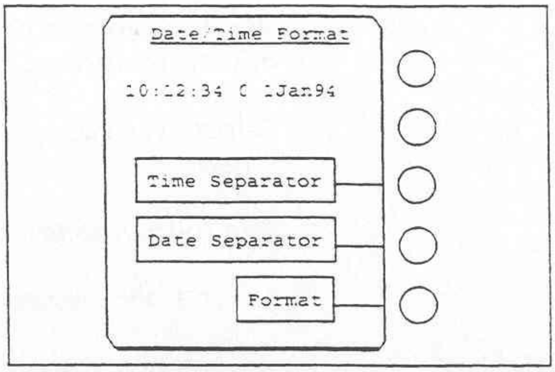
The second page of the Configuration Menu appears:


Select Language
Select Printer
Set Date/Time Format
Define Sample ID Character Sets

Step 2

Select `[Set Date/Time Format]`.

The Date/Time Format screen appears, showing the system's default date and time:


Date/Time Format
10:12:34 01Jan94
Time Separator
Date Separator
Format

**NOTE:** If you do not want to change the current time separator, go to Step 5.

Step 3

Select `[Time Separator]` on the Date/Time Format screen.

The following selections appear:

- `[ : ]` (colon)
- `[ . ]` (period)
- `[ , ]` (comma)

Step 4

Select a time separator.

The display automatically returns to the Date/Time Format screen.

**NOTE:** If you do not want to change the current date separator, go to Step 7.

Step 5

Select `[Date Separator]` on the Date/Time Format screen.

The following selections appear:

- `[ / ]` (slash)
- `[ - ]` (dash)
- `[ . ]` (period)

Step 6

Select a date separator.

The display automatically returns to the Date/Time Format screen.

**NOTE:** If you do not want to change the current date/time format, go to Step 9.

Step 7

Select `[Format]` on the Date/Time Format screen.

The following selections appear:

- `[HH.MM ddmmm]`
- `[HH.MM ddmmmyy]`
- `[HH.MM yy/mm/dd]`
- `[HH.MM.SS ddmmmyy]`
- `[HH.MM mm/dd/yy]`

Press the <DOWN> arrow key to display the next selection.

- `[HH:MM dd/mm/yy]`

**NOTE:** The date and time separators used in this display are those that you selected in Step 5 above.

Step 8

Select a date/time format.

The display automatically returns to the Date/Time Format screen.

Step 9

Press the <Previous Screen> key to return to the Configuration Menu.

## Defining the Sample ID Character Sets

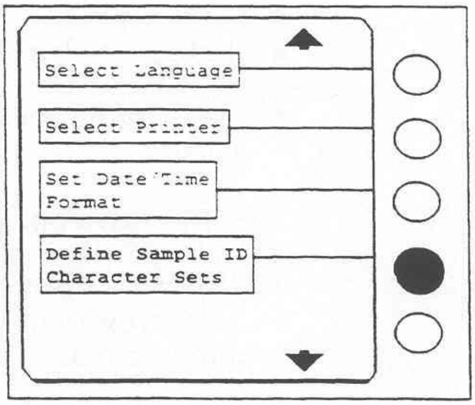
This option lets you define two separate three-character ID sets. Use one or both of these sets to input repetitive characters for sample IDs.

Step 1

Press the <DOWN> arrow key from the first page of the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

The second page of the Configuration Menu appears:



Step 2

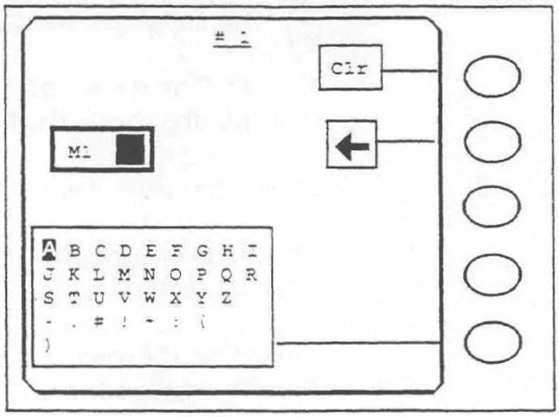
Select `[Define Sample ID Character Sets]`.

The following selections appear:

- `[Sample ID Set 1]`
- `[Sample ID Set 2]`

Step 3

Select one of the two character sets to define. The following screen appears:



The space next to the "Z" character can be used to create a space in your ID set.

Step 4

Press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box.

Step 5

Press the [selection key] for the character box to select the character, which then appears in the cursor box.

Step 6

Repeat Steps 4 and 5 to add up to two additional characters to the ID.

Alternately, use these functions:

- `[Clr]` to clear the box containing the cursor
- `[←]` to delete one character in front of the cursor

Step 7

Step 7 has two options:

- If you are finished defining sample ID character sets, press the <Previous Screen> key three times to exit to the Configuration Menu.
- If you want to define the other ID character set, press the <Previous Screen> key one time and return to Step 3.

## Selecting a Bar Code Reader Wand

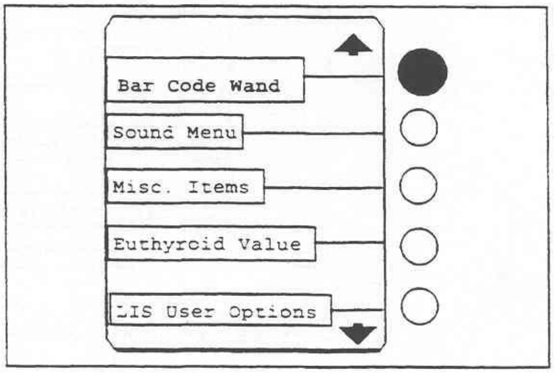
If you elect to use a bar code reader wand with your mini VIDAS, configure the system using this procedure, then install the reader following the instructions in Appendix C.

Step 1

Press the <DOWN> arrow key twice from the first page of the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

The third page of the Configuration Menu appears:



Step 2

Select `[Bar Code Wand]`.

Selections similar to the following appear:

- `[None]` (the default setting)
- `[Barcode Wand]`

**NOTE:** The current selection is indicated by the ☒ symbol.

Step 3

Select a [bar code wand].

Step 4

Press the <Previous Screen> key to return to the Configuration Menu.

## Miscellaneous Items

This option is used to select or deselect various warnings and notifications concerning Master Lot data and Standards.

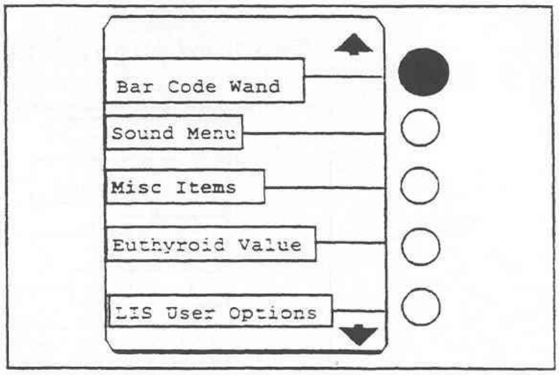
**NOTE:** In the default configuration, all of the miscellaneous options are enabled except the two for **Expired Standard Printed Warnings**, and **Autoprint Errors.**

Step 1

Press the <DOWN> arrow key twice from the first page of the Configuration Menu.

**NOTE:** See page 2-6 for accessing the Configuration Menu.

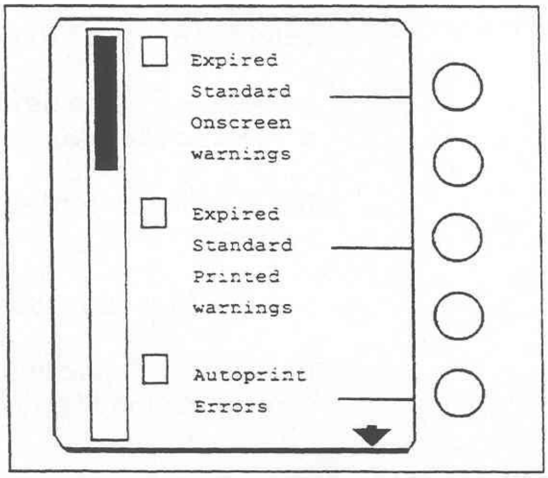
The third page of the Configuration Menu appears:


Bar Code Wand
Sound Menu
Misc Items
Euthyroid Value
LIS User Options

Step 2

Select `[Misc Items]`.

A screen similar to the following appears:


☐ Expired Standard Onscreen warnings
☐ Expired Standard Printed warnings
☐ Autoprint Errors

Step 3

Step 3 has seven options.

**NOTE:** An `[X]` appears in the box for each selected option. The `[X]` is removed when you deselect a selected option.

Step 3 continued

Each option is independent of the others. Therefore, more than one option may be selected.

- Select `[Expired Standard Onscreen warnings]`.

The system will generate an error message when a standard expires. The error message is displayed the next time the power is turned on and at each 24 hour cycle.

**NOTE:** See Section 7, Error Handling, for more information on error messages.

- Select `[Expired Standard Printed Warning]`.

The system will generate an error message when a standard expires. The error message is printed when the system power is turned on and at each 24 hour cycle.

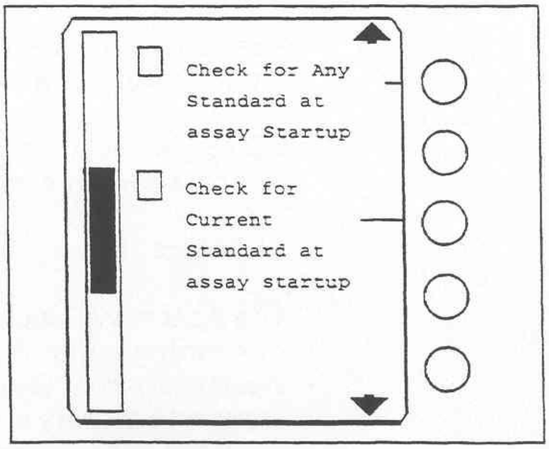
**NOTE:** See Section 7, Error Handling, for more information on error messages.

- Select `[Autoprint Errors]`.

The system will generate a printout when an error occurs. You will still need to view the error on screen to stop the blinking and beeping. If you do not select this option, messages are printed only after the operator acknowledges the error.

**NOTE:** See Section 7, Error Handling, for more information on error messages.

Press the <Down> arrow key to display the next screen. The following selections appear:


☐ Check for Any Standard at assay Startup
☐ Check for Current Standard at assay startup

- Select `[Check for Any Standard at assay Startup]`.

The system generates a startup error only when no standard, current or expired, exists for the selected assay.

**NOTE:** See Section 7, Error Handling, for more information on error messages.

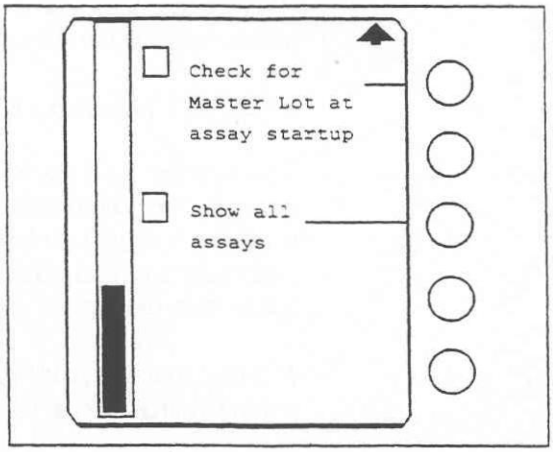
- Select `[Check for Current Standard at assay Startup]`.

The system generates a startup error if there are no current standards for the selected assay.

**NOTE:** See Section 7, Error Handling, for more information on error messages.

Step 3 continued

Press the <Down> arrow key once more to display the last screen. The following selections appear:



☐ Check for Master Lot at assay startup

☐ Show all assays

- Select `[Check for Master Lot at assay Startup]`.

The system will generate a startup error when there is no Master Lot data for the selected assay.

**NOTE:** See Section 7, Error Handling, for more information on error messages.

- Select `[Show all assays]`.

The system will include all of the assays it is capable of running when it displays an assay selection list. Deselect [`Show all Assays`] when you want the system to display only the assays for which Master Lot data has ever been entered.

**NOTE:** A change to this option does not take effect until the system is rebooted.

Step 4

Press the <Previous Screen> key to return to the Configuration Menu.

## Setting FTI Euthyroid Reference Value

The Free Thyroxine Index (FTI) is a calculated result using T4 and T Uptake (TU) results. FTI results are based on the following formula:

$$FTI = \frac{T4 \ X \ TU}{R}$$

In the formula, "R" is the FTI Euthyroid Reference Value. The system assigns this reference a default value of 100.

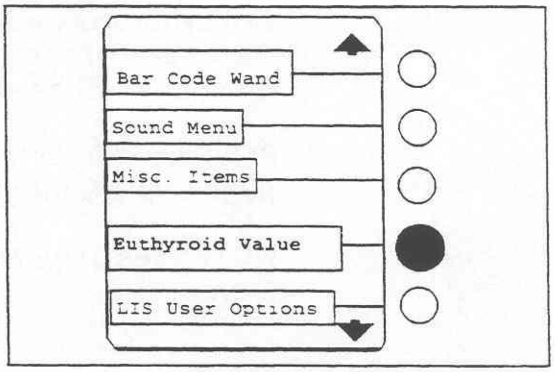
The following procedure allows you to change this reference value.

Step 1

Press the <DOWN> arrow key twice from the first page of the Configuration Menu.

NOTE: See page 2-6 for accessing the Configuration Menu.

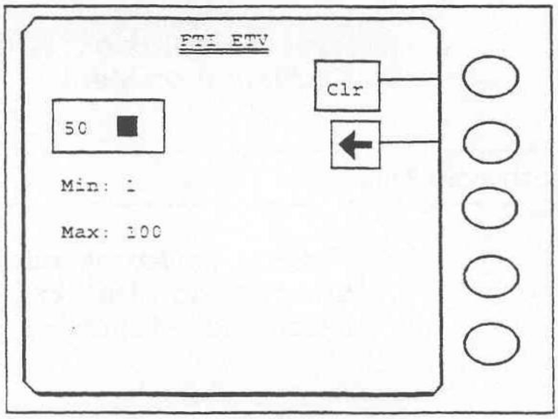
The third page of the Configuration Menu appears:



Step 2

Select [Euthyroid Value].

The FTI ETV screen appears:



FTI ETV

50

Min: 1

Max: 100

Step 3 Enter a new [FTI Value].

Step 4 Press the <ENTER> key.

The display returns to the Configuration Menu.

Step 5 Press the <ENTER> Key to return to the Main Menu.

★ See Chapter 5, Results and Reports, for the procedure on printing an FTI report.

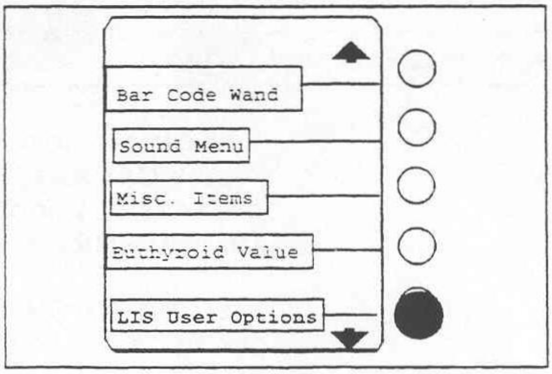
## LIS User Options

This option is used if your mini VIDAS is connected to a Laboratory Information System (LIS). Before results can be sent to the LIS, the LIS upload function must be enabled.

Step 1 Press the <DOWN> arrow key twice from the first page of the Configuration Menu.

**NOTE**: See page 2-6 for accessing the Configuration Menu.

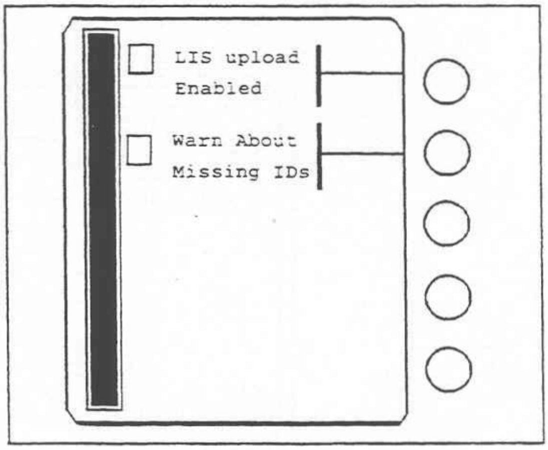
The third page of the Configuration Menu appears:


Bar Code Wand
Sound Menu
Misc. Items
Euthyroid Value
LIS User Options

Step 2

Select `[LIS User Options]`.

A screen similar to the following appears:


☐ LIS upload Enabled
☐ Warn About Missing IDs

Step 3

Select `[LIS upload Enabled]`.

This selection will activate the Laboratory Information System (LIS) upload feature.

**NOTE:** An `[X]` appears in the box for each selected option. The `[X]` is removed when you deselect a selected option.

Step 4

Step 4 is optional.

Select `[Warn About Missing IDs]`.

When this option is selected, assays are checked at assay startup. If an assay does not have an ID, a warning message is generated. Acknowledging the message allows the assay to continue. You can then add an ID to the assay. If this option is not selected, no ID warning messages are generated.

Step 5 Press <ENTER> to return to the Main Menu.

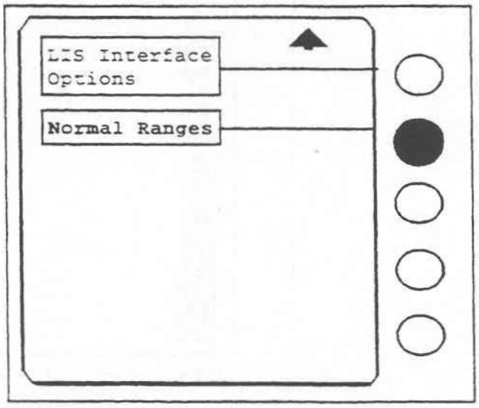
## Creating Normal Ranges for Assays

You can create up to eight lines of free text for any mini VIDAS assay. These lines, each with up to 36 characters, is printed at the bottom of each report for the particular assay type.

Step 1 Press the <DOWN> arrow key three times from the first page of the Configuration Menu.

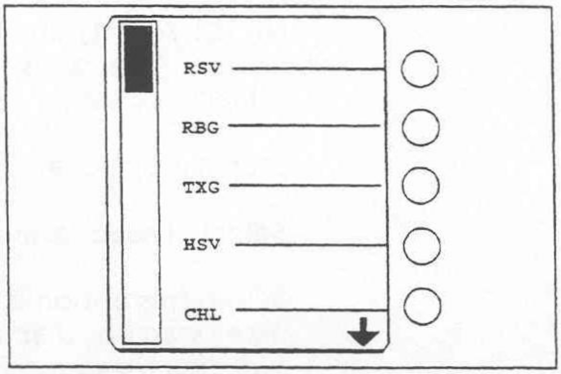
**NOTE:** See page 2-6 for accessing the Configuration Menu.

The fourth page of the Configuration Menu appears:



Step 2 Select `[Normal Ranges]`.

An assay selection screen appears*:



---

* The assays that actually appear may be limited by the `[Show All Assays]` configuration option, described earlier in this chapter.

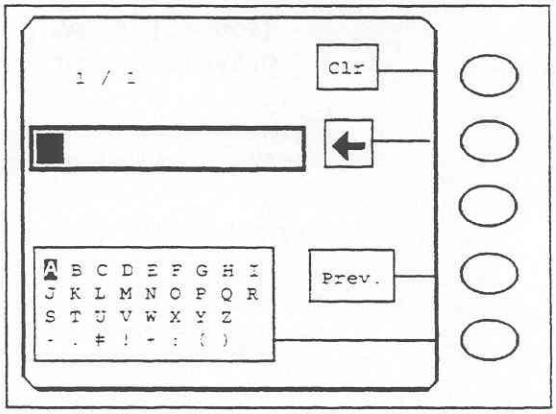
Step 3

Optional. Press the <DOWN> or <UP> arrow keys, as needed, until the assay you want appears on the screen.

Step 4

Select [an assay] whose normal ranges you want to create.

The following screen appears:



The "1 / 1" in the upper left portion of the display tells you that this screen is for Line #1 of 1 total lines. These numbers change as you access the screens for other lines.

Step 5

Press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box.

The space next to the "Z" character can be used to create a space in your text.

Step 6

Press the [selection key] for the character box to select the character, which then appears in the cursor box.

Step 7

Repeat Steps 5 and 6 to add up to 36 characters.

Alternately, use these functions:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor
- `[Prev.]` to switch to the screen for the previous line of text.

Step 8

Optional. Select `[Enter]` to switch to the screen for the next line of text.

Repeat Step 5 to 7 to enter up to eight lines of text.

Step 9

Press the <Previous Screen> key to exit to the Configuration Menu.

### Backing Up Your Configuration Settings

The mini VIDAS saves the configuration options you set in permanent storage. It is recommended, however, that you perform a backup of these settings so that they can be easily restored, if required.

★ The procedures for backing up and restoring mini VIDAS configuration options (and other data) are located in Chapter 6, Miscellaneous Operations.)

## Installing Paper in the Printer

Use this procedure to load paper in the internal thermal printer.

**NOTE:** The paper for this printer is coated on only one side. If the printer does not print after the paper is installed, reorient the roll to expose the other side.

Step 1

Lift the printer door, located on the top of the instrument, above the keypad.

Step 2

Retrieve the paper spindle from its slots and put it through the core of the paper roll.

**NOTE:** If you have just unpacked the mini VIDAS, there may be a piece of tape holding the spindle. Remove and discard this tape.

Step 3

Return the loaded spindle to the vertical slots in the print roll housing.

Step 4

Slide the paper engagement lever to the **LOWER** end of its slot.

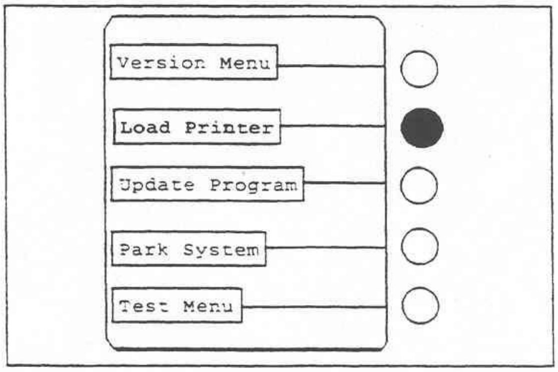
Step 5

Select `[Utility Menu]` on the Main Menu.

Step 6

Select `[Misc. Functions]` on the Utility Menu.

The Miscellaneous Functions Menu appears:



Step 7

Select `[Load Printer].`

The following message appears:

```
Load paper now...
```

Step 8

Push the edge of the paper under the paper feed roller.

There is a sensor that detects the presence of the paper, and activates the paper roller.

Step 9

Slide the paper engagement lever to the **UPPER** end of its slot.

Allow the roller to feed the paper. It stops automatically in a few seconds.

**IMPORTANT** The paper must be fed enough so that the leading edge extends under the plastic paper guide and out of the printer compartment so that it is exposed when you close the printer door. If necessary, select `[Load Printer]` another time to feed more paper.

Step 10 Hold the leading edge of the paper in one hand and with the other hand close the printer door.

Your mini VIDAS is now ready for use!

# 3. Parts of the System

## Introduction

This chapter presents an overview of the mini VIDAS system. Each section in the chapter provides a physical description of the system component. It also introduces you to the names of the various parts of the mini VIDAS system.

The topics included are

- The mini VIDAS Hardware 3-2
- The System Software 3-7
- The Assay Kit 3-17

## The mini VIDAS Hardware

The mini VIDAS is a completely self-contained unit, intended to be used with VIDAS assay kits.

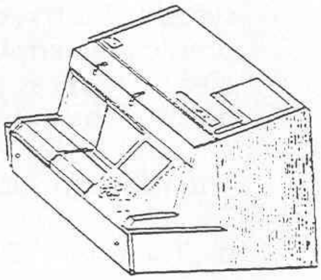


Figure 3–1 The mini VIDAS

The hardware system contains the following elements:

- Space to insert up to 12 Single or 6 Dual Reagent Strip tests
- A fluorometric optical system
- A bar code reader to read encoded information from the Reagent Strip label, Master Lot Data Cards, and Barcode Assay and Protocol (BAP) Cards
- A mechanical system that processes the tests
- An incubation system to maintain all components at required temperatures
- A central processing unit to control the entire system
- A keypad and screen
- A thermal printer

**Sections**

The analytical portion of the mini VIDAS contains two compartments called "Sections." Labeled A and B, the Sections operate independently, allowing a variety of tests to be run on the system at the same time.

### Reagent Strip Tray

On the lower portion of each Section, a plastic dust cover can be lifted to reveal the Reagent Strip tray. The tray, shown in the figure below, consists of six channels into which you can slide a Reagent Strip. Each of the six channels constitutes a Position in the Section. You can insert up to six Single, or three Dual Reagent Strips for a combined capacity of up to 12 tests. During processing, the tray is pulled into the instrument for processing.

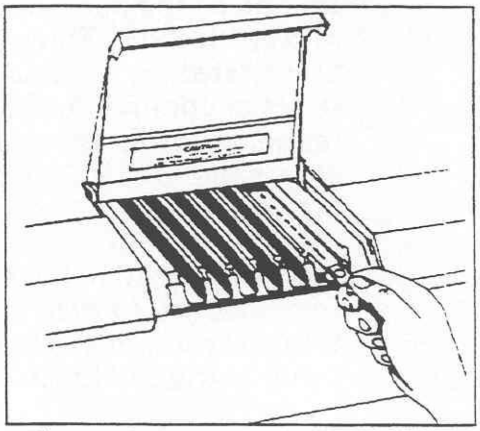


Figure 3–2 Reagent Strip Tray

The Reagent Strip Tray is also used to update the assay codes and protocols through the use of BAP cards (Barcode Assay and Protocol). BAP cards are sent to you periodically by bioMérieux Vitek.

★ See Section 6, Miscellaneous Operations, in this Manual for more information on the BAP Card.

### SPR Compartment

The upper portion of a Section has a door that pulls down to reveal the SPR compartment. The main feature of this compartment is the six-position SPR block, used to hold the SPRs, or Solid Phase Receptacles. The six positions of the block correspond to the six positions in the Reagent Strip tray. During processing, the SPR block and SPR form a pipetting system that is used in the various steps of the assay process.

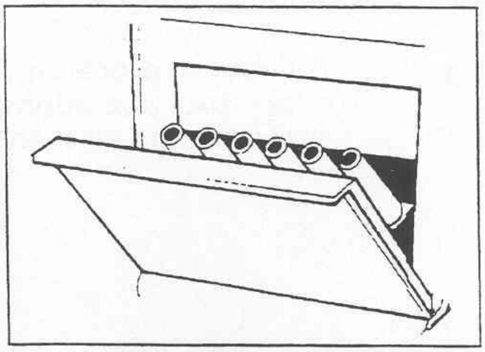


Figure 3–3 SPR Compartment

Operating Status Light

A small light above the SPR compartment door indicates the operating status of each Section. When the Section is running a test, the light is on; when the light is off, the section is idle. A flashing light indicates that the tests in that Section are completed, and that the Reagent Strips and SPRs should be removed.

Microprocessor

In addition to the central processing unit, each Section of the mini VIDAS contains its own microprocessor. This unit is responsible for storing and operating the assay Protocols. A Protocol is a series of commands that include the mixing of reagents, washing steps, and optical readings. It allows the mini VIDAS to perform a complete automated assay.

Incubators

The assays used in the mini VIDAS require temperature control. Two systems control temperature, one in the Reagent Strip tray and the other in the SPR block.

★ For information on temperature monitoring in the mini VIDAS, see Chapter 7.

**Detection System**

The mini VIDAS uses a fluorometric scanner as the detection system. The scanner is mounted on a mechanical device that permits it to be used for both Sections. The system detects chemical changes in the specialized optical cuvette mounted at the end of every Reagent Strip.

The figure below shows the position of the optical cuvette in a typical Reagent Strip.

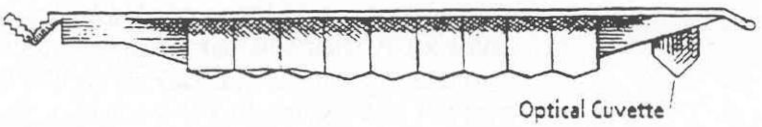


Figure 3–4 Optical Cuvette on a Reagent Strip

**Central Processing Unit**

The central processing unit controls all aspects of mini VIDAS operations, including data analysis, and control of the mechanical and optical systems.

## Keypad and Screen

The keys on the mini VIDAS console are almost completely flat. When depressed, they produce a "click" that can be heard and felt.

The screen is a liquid crystal type. It conveys all communications from the onboard computer. Immediately to the right of the screen are five touch keys that are used to select items presented on the screen.

The following figure shows the mini VIDAS keypad and screen.

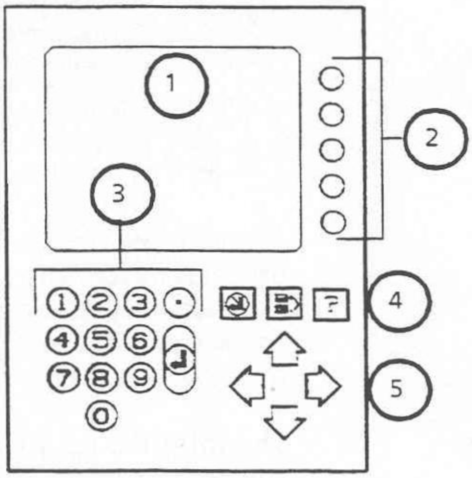


Figure 3–5 Keypad and Screen

| Reference | Description |
|---|---|
| 1 | Display screen. This is where all instructions and messages for operating the mini VIDAS are displayed. |
| 2 | Option selection keys. These five keys are used to select one of up to five options that can appear on the display screen. The options are displayed on the screen opposite the keys used to select them. |
| 3 | Numeric keypad. These keys are used to input numbers into the system, and, in some cases, to make input selections. They include the ten digits, 0 - 9, a decimal point, and an <ENTER> key. |

**NOTE:** The <ENTER> key, in addition to its use with the numeric keypad, can be used as a quick return to the Main Menu when a submenu is displayed on the screen.

4 Function keys. These three keys perform specific functions in the system.

? The key represented by a question mark is the help key. Press this key once to display information for the screen on which you are working, or twice for a Help Mode Screen that provides the following :

- Print Screen
- System Status
- Information
- Assay compatibility list.

This key is also used to display error messages.

This key is used to return to the previous screen during a procedure. It can be used to return to a particular menu or to correct a selection error.

This key is used to UNDO a keypad input. In some cases, it deletes the last input made and returns you to the previous operation.

5 Arrow keys. These keys are used to move the cursor on certain screens. The <UP> and <DOWN> keys are also used to page the display screen, that is, to show a second or third page of output that does not fit on one screen.

**Internal Printer**

The mini VIDAS includes an internally mounted thermal printer. The printer is located on the top of the system, directly above the keypad and screen.

**Rear Panel Components**

The rear panel of the mini VIDAS contains several important hardware components. The location of these components is shown in the following figure:

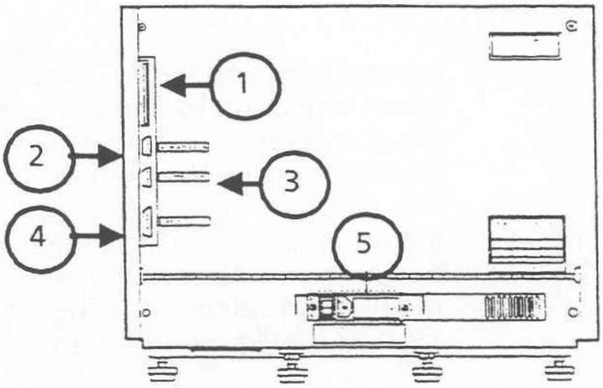


Figure 3–6 mini VIDAS Rear Panel

| Reference | Description |
|---|---|
| 1 | Memory card slot. This slot is the receptacle for the mini VIDAS software update cards. A memory card is sent to you to perform updates of the mini VIDAS system software when required. |

2 Diagnostic port. This cable connection is used to troubleshoot the system and is not part of normal operation. The optional bar code wand is connected via this port.

3 Computer port. This cable connection can be used to connect the mini VIDAS to a computer. Assay results are then sent to that computer via this connection.

4 Printer port. This cable connection can be used to connect the mini VIDAS to an external printer. A PC compatible cable and Epson compatible printer are required.

5 AC power connection. This section of the rear panel contains the hardware for connecting the mini VIDAS to an AC power source. It includes

- On/off switch
- Receptacle for an AC power cord
- Fuse compartment

## The System Software

### The mini VIDAS Menu System

The mini VIDAS is a menu-driven system, that is, all of the parts of the software program are selected from a menu, rather than by entering commands. The figure below, for example, shows the Main Menu.

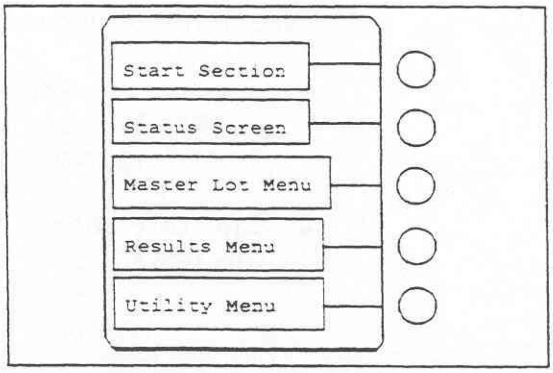


Figure 3–7 mini VIDAS Main Menu

### Selecting a Menu Option

Five selection keys, located to the right of the screen, enable you to select options on mini VIDAS menus. Since not all displays use all five selection keys, the boxed selections and lines indicate the active keys. This display uses one of two methods to show the active keys.

The figure above illustrates the first method. Notice that each option is in a box with a line extending to a selection key.

The other method of showing active selection keys is used where additional information appears between the option and the selection key. The following figure shows the status screen for the two mini VIDAS Sections, A and B. The Sections represent two of the three selection options on this screen; the text is status information for each Section.

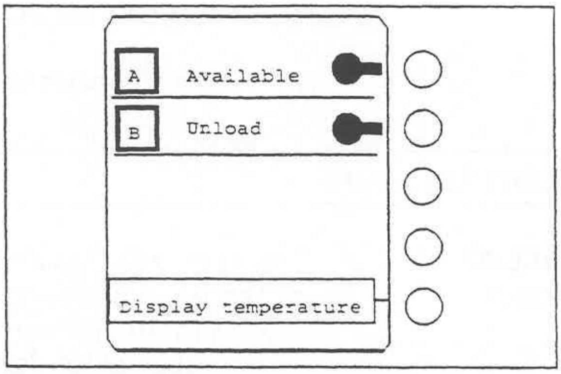


Figure 3–8 Showing Active Selection Keys

Two things to note on this screen are

- The active selection keys are noted by the marker "•–" and the enclosed box with a line extending to a selection key
- Only three of the five selection keys are active on this screen

Menu System Structure

The diagram below shows the entire structure of the mini VIDAS menu system. Notice that VIDAS Main Menu, as the entry point into the system, also serves as the pathway to the other menus in the system. Several of the selections on the VIDAS Main Menu are other menus. This is reflected in the structure diagram below.

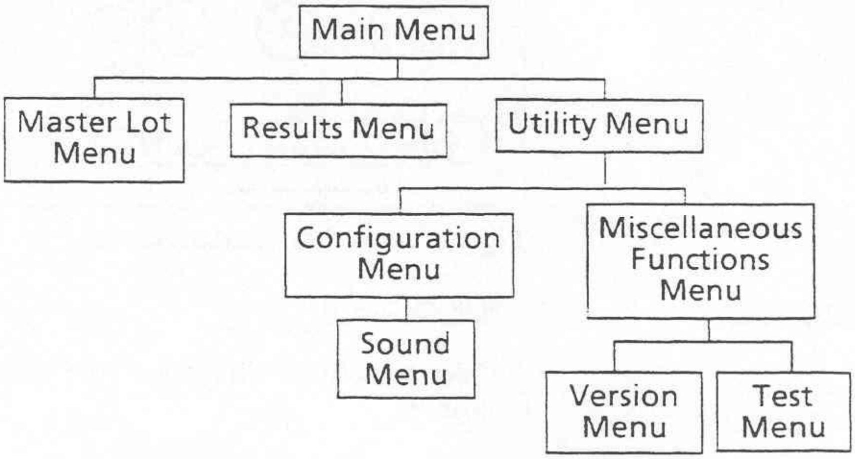

Main Menu
Master Lot Menu
Results Menu
Utility Menu
Configuration Menu
Miscellaneous Functions Menu
Sound Menu
Version Menu
Test Menu

Figure 3–9 mini VIDAS Menu Structure

When a menu is accessed from another menu, it is called a **submenu.** Each submenu in the mini VIDAS system contains a particular group of programs that are related. The Configuration Menu, for example, contains all the programs that set the configuration of the VIDAS system. The programs on the mini VIDAS Main Menu are those we think you will use most often.

**The Status Screen**

The second item on the mini VIDAS Main Menu is labeled "Status Screen." This display is used to indicate the current status of the two Sections in the mini VIDAS, and to assign assays to them. The status screen is also used to display the temperature of each section's tray and SPR compartment. Knowing how to read the status screens is an important part of operating the system.

The first status screen is shown in the following figure.

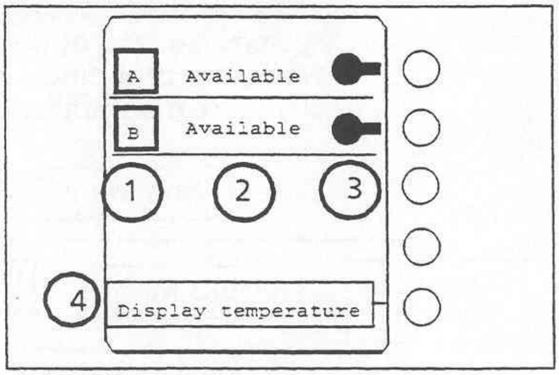


Figure 3–10 First Status Screen

| Reference | Description |
|---|---|
| 1 | Section labels. There are two Sections, labeled A and B. |
| 2 | Section status. The status of each Section. The following status indicators are used:<br>● Available. The Section is available to be assigned and run tests.<br>● Bar Code. The VIDAS Module is in the process of reading the bar codes of the Reagent Strips in the Section.<br>● Error. Indicates a temperature control problem or other hardware problem in the Section.<br>● Master Lot. The mini VIDAS is reading Master Lot data from a Master Lot Data card.<br>● Offline. The Section has been taken offline.<br>● Resetting. The Section is in the process of a hardware reset and is not available. This status normally lasts for less than one minute.<br>● Run. The Section is processing tests.<br>**NOTE:** When a Section is running, the following additional information appears on the screen:<br>– Assay code of the assay in the Section (if all the assays in that Section are the same)<br>– The estimated time of day that the run is expected to finish |

2, continued

- Start Error. There is an error related to the preprocessing of a Reagent Strip. Press the <?> key to display the status of each Position in the Section. Possible start errors are:
    - Bad Bar code. The system was unable to read the bar code on the Reagent Strip . It must be entered manually.
    - Bad Sub. The initial fluorescence reading of the substrate is not acceptable. The Reagent Strip must be replaced.
    - Incompatible. The assay in this Position is not compatible with other assays in the Section.
    - Misaligned. A Dual Reagent Strip has been placed in the wrong Positions. Dual Reagent Strips must be placed in Positions 1 & 2, 3 & 4, or 5 & 6.
    - Okay. There is no error in this Position.
    - No Strip. A Reagent Strip was specified for this Position but none was found.
    - Unknown Assay. There is no protocol stored in the system for the assay type.
    - Wrong Type. The type of assay specified for this Position is different than the one found.
- Starting. The Section has completed the preprocessing steps and is preparing to run tests.
- Unload. The Section is waiting for the SPRs to be removed. This occurs at the completion of a run, and is accompanied by the blinking of the Operating Status Light located over the SPR compartment door.

3 The "●–" marker. Indicates that a selection key is active to select a Section.

4 Display temperature. A screen is displayed showing the internal temperature of each Reagent Strip tray and SPR compartment.

**The Second Status Screen**

The second status screen is accessed by selecting one of the two Sections on the first screen. The purpose of the second status screen is to display the tests you have assigned to each Position within the Section.

The figure below shows a second status screen after all six Positions have been assigned.

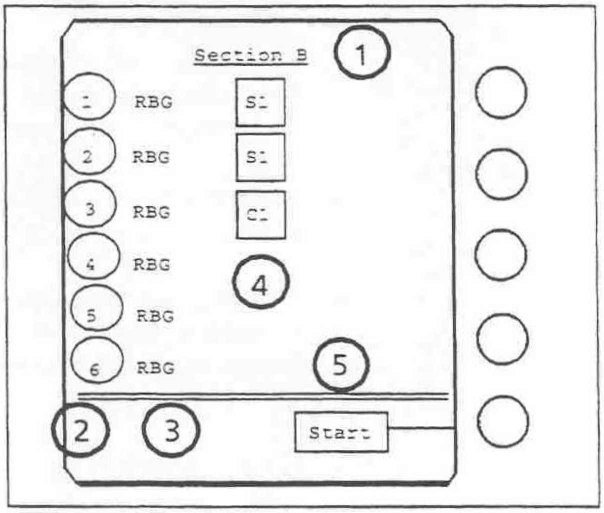


Figure 3–11 Second Status Screen

| Reference | Description |
|---|---|
| 1 | Screen label. This label shows you are looking at the status of Section B. |
| 2 | Position numbers. These numbers identify the six Positions in the Section. |
| 3 | Assay code. These codes appear as tests are assigned to the Section. |
| 4 | Standards, controls. If a Position is assigned to a standard or control, this type of designator appears. |
| 5 | Start. A selection option to start processing. |

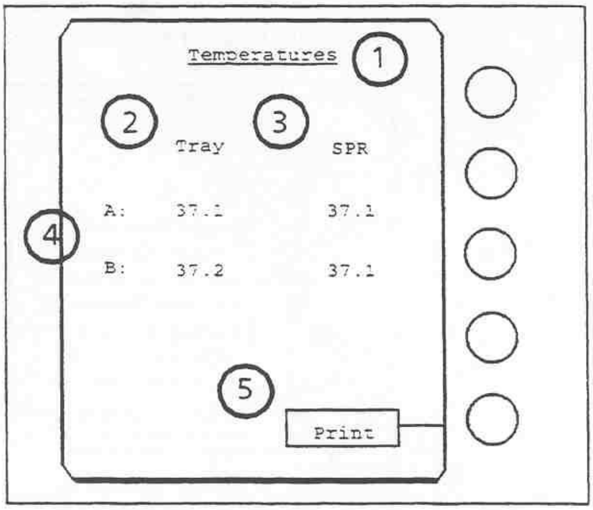
In other circumstances, this selection may have another function:

- Halt. This function appears while the Section is processing. Use it to halt the processing.

**The Third Status Screen**

The third status screen is accessed by selecting `[Display Temperature].` The purpose of this screen is to inform you of the operating temperature of the SPR compartment and the Reagent Strip Tray compartment of each Section.

The figure below shows a typical third status screen.



| | Tray | SPR |
|---|---|---|
| A: | 37.1 | 37.1 |
| B: | 37.2 | 37.1 |

Figure 3-12 Third Status Screen

| Reference | Description |
|---|---|
| 1. | Screen label. This label shows you are looking at the Temperature screen. |
| 2. | Reagent Strip Tray column. This column shows the temperature of the tray compartment for each Section. |
| 3. | SPR column. This column shows the temperature of the SPR compartment for each Section. |
| 4. | Sections. These rows show the Sections. |
| 5. | Print. This selection allows you to print a copy of the Temperature screen. |

## Online Help

You can display information on the menu or program you are using by accessing the online help function. Pressing the <?> key on the keypad activates this function. You will first get a brief description of the screen from which you accessed the help function.

If you then press the <?> key a second time, the following screen appears:

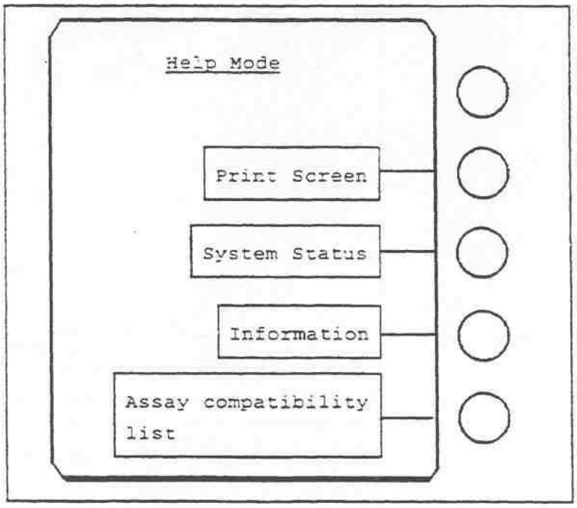


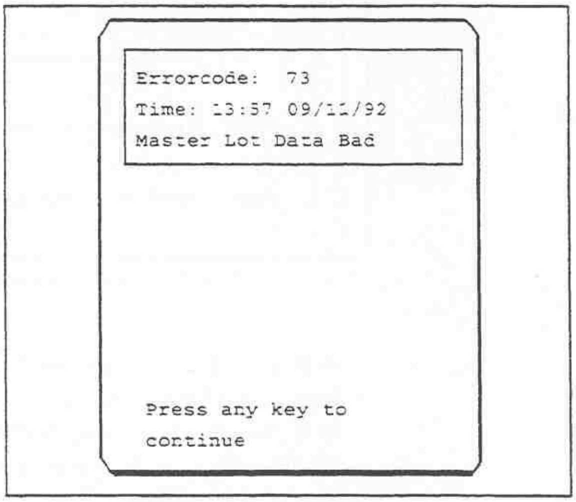
Figure 3–13 Help Mode Screen

This Help Mode screen provides the following functions:

- Print screen. Creates a printout of the screen from which you accessed the help function.
- System status. Displays the current Date/Time, and instrument condition.
- Information. Displays the first help screen.
- Assay compatibility list. Displays a list of mini VIDAS assays codes, showing the assays with compatible protocols.

## Viewing Error Messages

The <?> key also functions to display help messages. Should something happen on your system that requires your attention, the mini VIDAS will start to beep. When you press the <?> key in this mode, the screen displays an error message. The following figure is one example of the type of display you see:

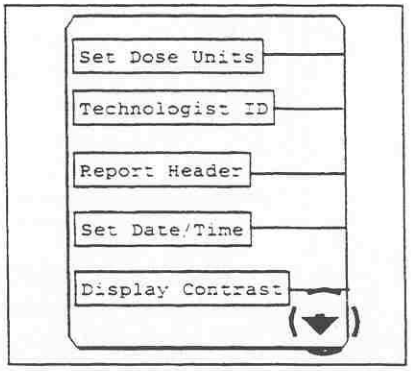


```
Errorcode:  73
Time: 13:57 09/11/92
Master Lot Data Bad

Press any key to
continue
```

## Screen Paging

Some of the displays in the mini VIDAS system are too long for one screen. In these cases you can page the screen display, using the <UP> and <DOWN> arrow keys.

The following figure, showing the Configuration Menu, illustrates this function:

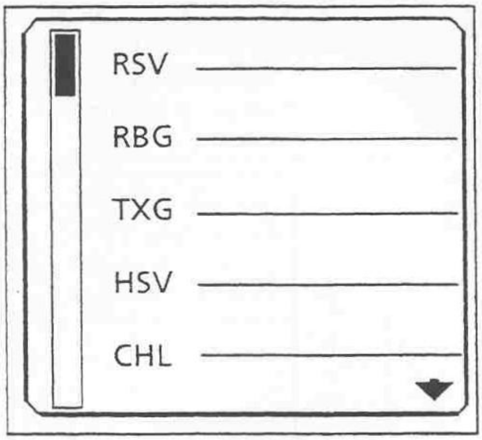


Note the arrow (circled) on the screen. When this arrow appears, press the <DOWN> key to display additional items.

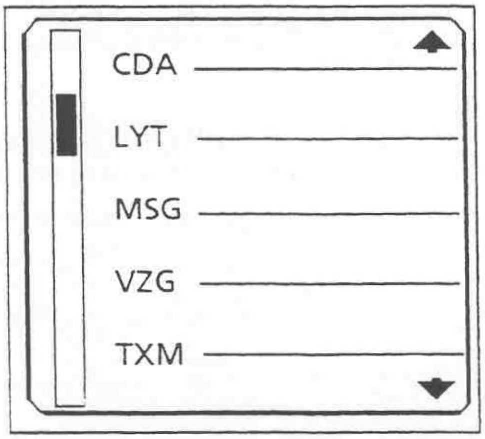
After the <DOWN> key is pressed, another arrow appears at the top of the display, indicating that you can use the <UP> key to page the display back.

## Paging Bar

Some mini VIDAS screens have what is called a paging bar, as illustrated in the following figure:



A paging bar is generally used for displays that require several screens. As you page down to the last page, the solid bar moves down the slot. Its position is relative to your position within the possible pages. The next page of this display would be similar to the following figure:



## Memory Cards

A memory card is a storage device for software, similar to the more familiar floppy disk. The mini VIDAS uses this type of device because of its small size and convenience.

Memory cards are used to perform software updates. Should the system software for your mini VIDAS be updated, bioMérieux Vitek will send you a program update memory card. A special program takes the software from this card and places it in the system's internal memory for permanent storage.

**CAUTION** Memory cards must be kept from moisture, extreme temperatures, and direct sunlight. They should not be subjected to flexing or severe impacts.

## The Assay Kit

Each mini VIDAS assay kit provides the materials required to run a specific assay. The materials vary for each assay, but generally a kit contains:

- Single or Dual Reagent Strips
- SPRs (Solid Phase Receptacle)
    - One per Single Reagent Strip
    - Two per Dual Reagent Strip
- Controls
- Standards, as required
- Sample treatment reagents, as required
- A package insert
- Master Lot Data Card or TOS Sheet

**Single Reagent Strip**

The mini VIDAS Single Reagent Strip has ten wells. The first one is an empty well in which to place the sample. The next eight wells contain reagents or washes. The last well is an optical cuvette where the substrate reaction is measured from its fluorescent reading.

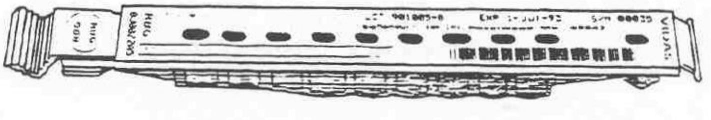


Figure 3–14 Single Reagent Strip

**Dual Reagent Strip**

Some assays use a Dual Reagent Strip, two strips attached side by side. The sample is equally divided between the two sample wells of the Dual Reagent Strip. With the strip oriented as shown in the figure below, the strip on the top is the sample reference strip. The one on the bottom is the sample test strip. The Dual Reagent Strip configuration is used to compensate for sample variability. The sample test strip contains a reagent that is not included in the sample reference strip. Measurements taken from both strips are used to determine the test result. Dual strips fit in the Reagent Strip Tray exactly like single strips, but they require two channels.

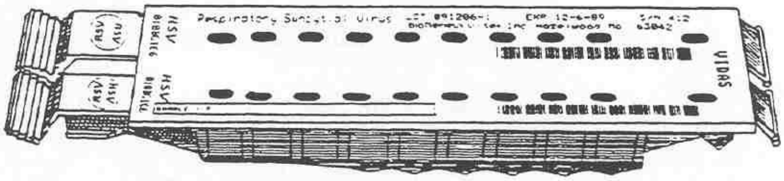


Figure 3–15 Dual Reagent Strip

**The Label**

Each mini VIDAS Reagent Strip has a label and a colored dot and the assay code. The color-coded dot corresponds to a matching dot on the test's companion SPR. The bar code identifies the assay name, the manufacturing lot number, the sequence number, and the expiration date of the test kit for the system. The following figure represents a typical label.

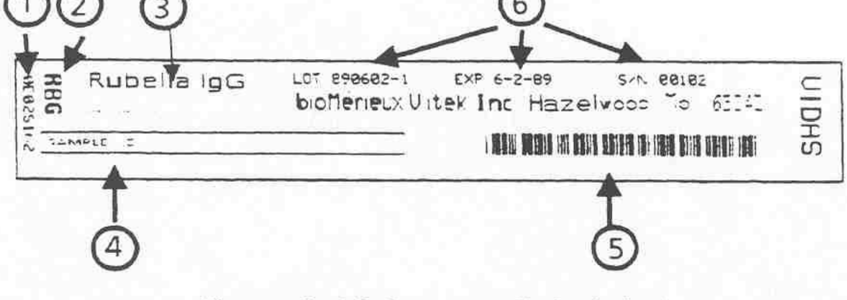


Figure 3–16 Reagent Strip Label

| Reference | Description |
|---|---|
| 1 | Bar code. The alphanumeric representation of the bar code, for use in manual bar code entry. |

2 Assay code. A two- to four-letter code symbolizing the assay name.

3 Assay name. The formal name of the assay.

4 Sample ID. Open space provided to write a sample ID number.

5 Bar code. Machine-readable bar code.

6 Header. Information concerning the Reagent Strip, including lot number, expiration date, and sequence number.

### Bar Code

The Bar Code appears twice on every label. One is in machine-readable form and the other is in a standard alphanumeric format.

Both forms of the bar code contain the identical information. Under normal operating conditions, the internal bar code reader scans the machine-readable code. If the system is unable to read that code, however, the alphanumeric format is available so that you can manually enter the data.

A bar code provides the following information about the Reagent Strip:

- Assay code
- Reagent Strip sequence number
- Assay kit lot number
- Assay kit expiration date

### Assay Code

The two- to four-letter Assay Code is an abbreviation of the full assay name. Some examples are

- RBG Rubella IgG
- TXG Toxoplasma gondii IgG
- CHL Chlamydia

All references to an assay within the software system and on printed reports use the Assay Code.

### Lot Number

The lot number is used within the system to encode the expiration date for the Reagent Strip lot. When this date is read from the bar code, mini VIDAS compares it with the system date to make sure that the lot has not expired.

## The SPR

The Solid Phase Receptacle, or SPR (pronounced "spur"), is a specially designed plastic pipette-shaped device.

During manufacturing, the interior of the SPR is coated with antibody, antigen, or other treatments that capture a target analyte. Each SPR has a corresponding mini VIDAS Reagent Strip included in the test kit; both are coded with matching color dots and assay code. It is critical that SPRs be paired only with strips that have matching dots. Otherwise, the test result will be invalid.

The figure below shows a typical SPR.

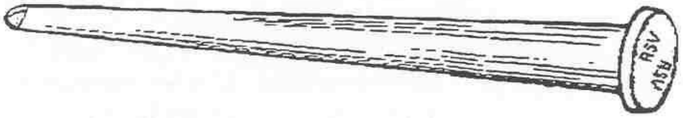


Figure 3–17 Solid Phase Receptacle (SPR)

### How the SPR Functions

The SPR block is part of an automated pipetting system that uses the SPRs to mix and transfer reagents during processing. The mini VIDAS uses the SPR to withdraw or dispense liquid from or to a well in the Reagent Strip. The beveled tip of the SPR enables it to pierce the protective seal that covers the wells in a Reagent Strip. The Reagent Strip tray then moves in and out to allow liquids to be transferred from one well to another.

The mini VIDAS uses the SPR to accomplish all the required processing steps, including sampling, mixing, and washing. For example:

- The sample is drawn into and out of the SPR.
- The target analyte from the sample binds to the SPR's interior coating (antibody, antigen, etc.).
- Various washes remove unbound and interfering substances.
- The target analyte is labeled by an enzyme-conjugated antibody, forming a "sandwich."

- The immobilized enzyme catalyzes the breakdown of the substrate into a fluorescent end product.
- The optical scanner obtains fluorescence readings of the substrate material and transmits the measurement to the central processing unit for analysis.

# 4. Routine Procedures

## Introduction

This chapter contains the procedures you need to perform the routine operations of the mini VIDAS. These procedures are concerned primarily with running assays, and include

- Planning a Run 4-2
- Running Assays 4-4
  - Starting a Load and Go Run 4-4
  - Starting a Defined Run 4-6
  - Assigning a Dilution Factor 4-12
- Listing Stored Standards 4-14
- Listing Master Lots 4-15
- Entering Master Lot Data 4-16
  - Automatic Data Entry via Master Lot Entry (MLE) Card 4-17
  - TOS Sheet Data Entry 4-18
  - Manual Data Entry 4-21
- Halting a Section 4-26

The procedures in this chapter assume that you have performed the following:

- Powered on the mini VIDAS.
- Set the system configuration options defined in Chapter 2.
- Prepared one or more Reagent Strips for processing, according to the instructions in the package insert for that assay kit.

## Planning a Run

The mini VIDAS has two Sections, each containing six Positions. That means you can run a total of 12 Single Reagent Strips, or 6 Dual Reagent Strips, at the same time. In planning the number and types of assays to run, you must consider four additional factors:

- Type of run required
- Assay compatibility
- Standards and controls
- Master lot data

### Type of Run Required

The mini VIDAS system allows two different types of runs. The first type of run is referred to simply as a defined run. The assays are defined in the system prior to the start of the run.

The second type is called a "Load and Go" run. No definitions are made prior to the run. The information that the system requires is taken from the labels on the Reagent Strips during the initial steps of the run.

#### Defined vs. Load and Go Runs

In addition to the assay type, two parameters can be entered prior to starting a defined run:

- Sample ID
- A standard or control

These two parameters can be entered in a Load and Go run, but only after it has been started. Your workload and procedural requirements will determine the type of run you use.

### Assay Compatibility

When planning a run, you may need to decide whether you can run different assay types at the same time. The mini VIDAS system allows you to run different assays in the two Sections at the same time. However, for different assays to run in the SAME Section, they must have compatible protocols.

There is a way to check if two assays are compatible. Use the following procedure to view the screen display of the assay compatibility list.

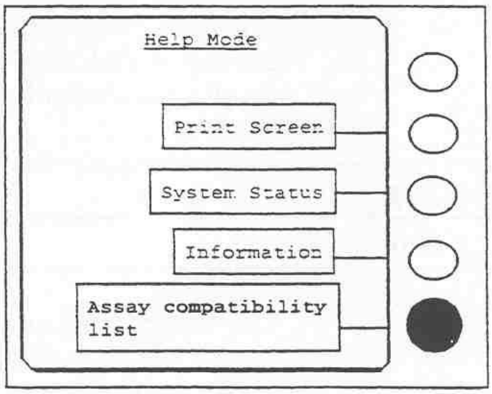
Step 1

From any screen, press the <?> key. A help screen appears.

Step 2

Press the <?> key a second time.

The following screen appears:



Step 3

Select `[Assay compatibility list].`

A list of assays appears on the screen. The assays listed in the same column are compatible with one another. If an assay is not on this list, it is not compatible with any other assay.

## Standards and Controls

Another part of your run planning is whether to include standards and controls.

### Standards

All Single Strip Reagent assays require that a standard assay result be stored in the system. There are two conditions where a standard must be included in a run:

- You are running an assay kit lot for the first time.
- The previous standard for the lot you are using has expired.

★ Refer also to the procedure Listing Stored Standards, later in this chapter.

### Controls

Positive and Negative Controls are provided in all VIDAS assay kits. Controls should be tested with each new lot or shipment to insure that assay performance has remained unimpaired throughout shipping storage. Controls should be tested routinely as specified by your laboratory's regulatory guidelines.

**TU/T4 Pairs**

If you are running TU/T4 pairs to obtain FTI reports, give the two tests matching sample IDs. This is a signal to mini VIDAS to pair them for the FTI report. If the tests do not have sample IDs, the test strips should be placed in corresponding positions in each tray. For example, if the TU test strip is placed in Position 1 of Section A, the T4 test strip should be placed in Position 1 of Section B. Other pairs should be placed in similar corresponding positions.

## Running Assays

### Starting a Load and Go Run

Use this procedure to start a run that does not require sample IDs, or standards or controls. The procedure assumes that all strips have been inoculated with appropriate samples. (See the appropriate package insert for sample preparation.)

Step 1

Insert the Reagent Strips:

- Lift the cover of the Reagent Strip tray.
- Holding a strip by its handle, insert it into its assigned test Position.
- Slide the strip all the way back; you will feel it seat in the Section channel.

Step 2

Insert the SPRs:

- Open the SPR compartment door.
- Place a SPR into the SPR block position directly over the corresponding Reagent Strip.

**NOTE:** Check the placement of SPRs and Reagent Strips. Make sure that the color-coded dot on each SPR matches the dot on the corresponding strip.

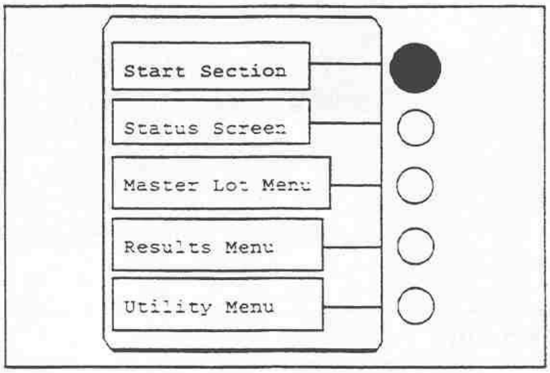
You must place all of the SPRs properly in the SPR block. The mini VIDAS cannot detect the presence or absence of SPRs. The prepared sample and Reagent Strip may be wasted if you do not follow this step.

Step 3

Close the SPR compartment door and the Reagent Strip tray cover.

Step 4

Select `[Start Section]` on the Main Menu:



The following selection options appear:

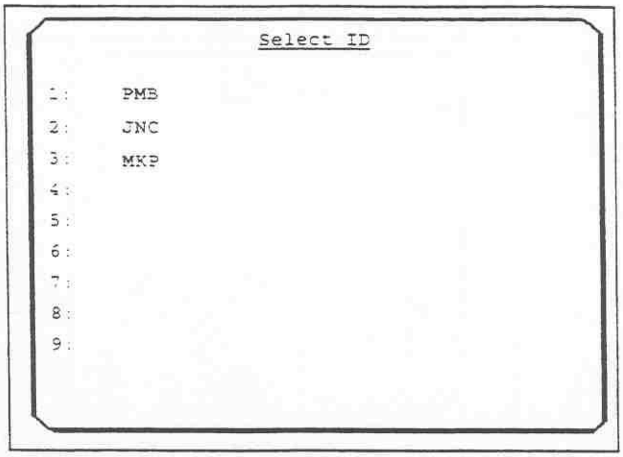
- `[Section A]`
- `[Section B]`
- `[All Sections]`

Step 5

Step 5 has two options:

- Select `[Section A]` or `[Section B]` to start one of the two Sections.
- Select `[All Sections]` to start Section A and Section B.

Regardless of the option you use, the following screen appears if two or more user IDs have been defined*:



```
                    Select ID

1:    PMB
2:    JNC
3:    MKP
4:
5:
6:
7:
8:
9:
```

---

* If only one user ID was defined, that ID appears on the assay report; if no user IDs were defined, no ID is included on the assay report.

★ See Configuring the mini VIDAS in Chapter 2 for more information.

Step 6

Press a digit on the <Number Key> pad corresponding to the user ID assigned to this Section.

The following message appears:

```
Starting Section please wait
```

The display returns to the Main Menu.

## Starting a Defined Run

This procedure includes all the steps required to define the tests in the system, load the strips and SPRs, and start the Sections. It does, however, assume that all strips have been inoculated with appropriate samples. (See the appropriate package insert for sample preparation.)

Step 1

Select `[Status Screen]` from the Main Menu.

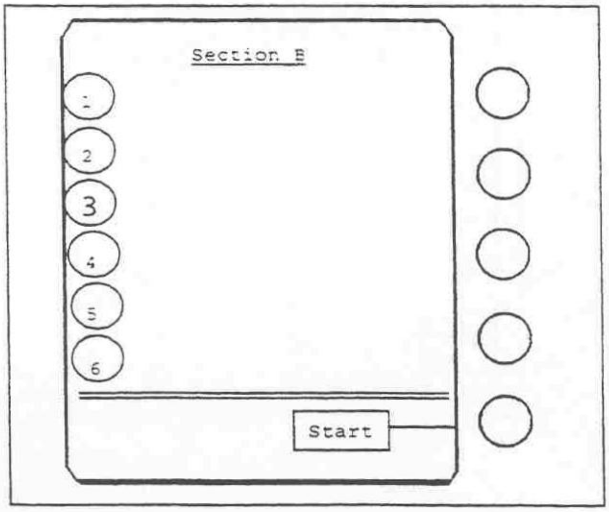
Step 2

Select **[Section A]** or **[Section B]**, depending on where you plan to place strips and SPRs.

**NOTE:** A Section must have a status of "Available" in order for you to proceed.

★ See Chapter 3 for a listing of status codes and their meanings.

After a Section is selected, the Section screen appears:



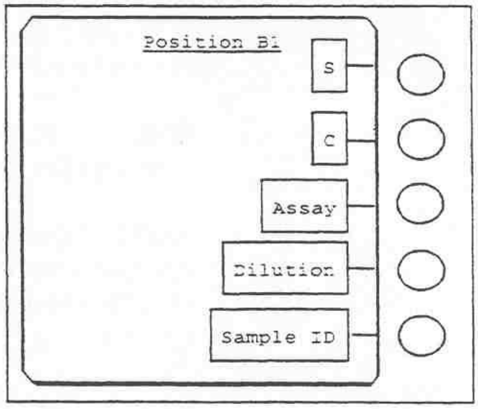
The numbers on the screen correspond to the six Positions in the Section.

Step 3

Press the <Number Key> corresponding to the Position where you want to place a Reagent Strip.

**NOTE:** Dual Reagent Strips **MUST** be placed in Positions 1 & 2, 3 & 4, or 5 & 6. Placing one in Positions 2 & 3, for example, causes an error.

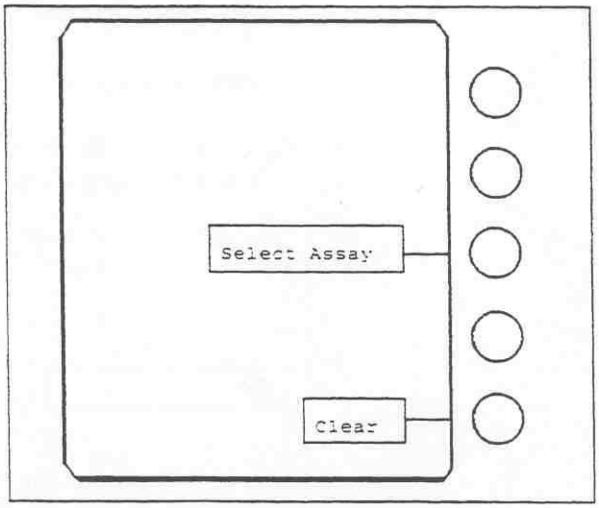
The Position screen appears:



Step 4

Select `[Assay]`.

The following screen appears:



Step 5

Select `[Select Assay]`.

An assay code list appears.

**NOTE:** If an assay has already been selected for the Section, the assay code list includes only those assays compatible with the assay previously selected.

Step 6

Press the <DOWN> arrow key, if necessary, until the assay code you want appears.

Step 7

Select the [assay code]. The Position screen returns with the assay code now included.

**NOTE:** If this test is **NOT** a standard or control, go to Step 9.

Step 8

Optional. Step 8 has two options:

- Select `[S]` if this test is to be a standard. The following prompt appears:

  ```
  Enter Standard number (1-9)
  ```

  Press a <Number Key> corresponding to the ID number for the standard.

  **NOTE:** Multiple standards with the same ID number are considered to be replicates by the system. Their results are averaged for use in calculating sample results.

- Select `[C]` if this test is to be a control. The following prompt appears:

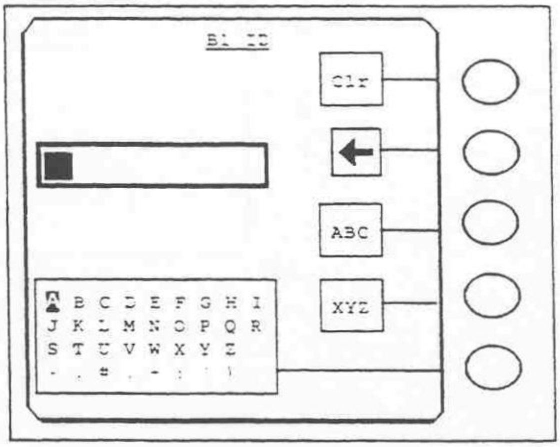
  ```
  Enter Control number (1-3)
  ```

  Press a <Number Key> corresponding to the ID number for the control.

Step 9

Select `[Sample ID]`.

A screen similar to the following appears. In this example, it is the sample ID screen for Section B, Position 1:



**NOTE:** The space next to the "Z" character can be used to create a space in your ID.

**Step 10**

Step 10 has two options:

- Enter the sample ID manually:
  - Press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box, then select the [character box].

    The character appears in the cursor box.
  - Press the appropriate <Number Key> to place a number in the cursor box.
  - Select one of the two [sample ID character sets] to place one of these character sets in the cursor box.

    ★ See Configuring the mini VIDAS in Chapter 2 for more information on Sample ID Character Sets.
- Use the optional bar code wand to input the sample ID.

**Step 11**

Repeat Step 10 until the sample ID for the test is complete. Up to 12 characters can be entered.

Alternately, use these functions:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor

**Step 12**

Press the <Previous Screen> key to return to the Position screen.

The sample ID now appears on that screen.

**Step 13**

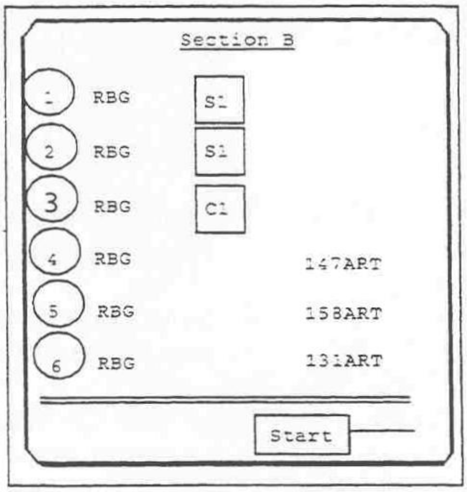
Repeat Steps 3 to 12 to define a test for the other Positions in the Section.

**NOTE:** The following functions are also available in this procedure:

- Select `[Clear]` on the Assay screen to erase the inputs for a Position, or to erase all the inputs for the entire Section.
- Press <ENTER> after defining a test to define the same assay type for the next Position.

Step 14

When all the Positions in a Section are defined, press the <Previous Screen> key to return to the Section screen. The following figure shows a Section screen with information defined for all six Positions:



Step 15

Insert the Reagent Strips:

- Lift the cover of the Reagent Strip tray.
- Holding a strip by its handle, insert it into its assigned test Position.
- Slide the strip all the way back; you will feel it seat in the Section channel.

**NOTE:** Make sure that the placement of the Reagent Strips matches the definitions you entered in this procedure.

Step 16

Insert the SPRs:

- Open the SPR compartment door.
- Place a SPR into the SPR block position directly over the corresponding Reagent Strip.

**NOTE:** Check the placement of SPRs and Reagent Strips. Make sure that the color-coded dot on each SPR matches the dot on the corresponding strip.

You must place all of the SPRs properly in the SPR block. The mini VIDAS cannot detect the presence or absence of SPRs. The prepared sample and Reagent Strip may be wasted if you do not follow this step.

Step 17

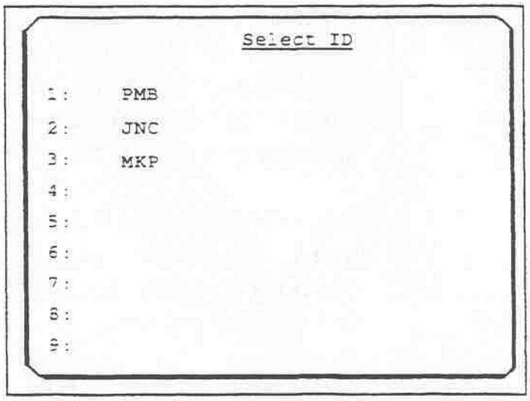
Close the SPR compartment door and the Reagent Strip tray cover.

Step 18

Step 18 has two options:

- Select `[Start]` to start the Section.

If two or more user IDs have been defined*, the following screen appears:



```
                    Select ID

1:    PMB
2:    JNC
3:    MKP
4:
5:
6:
7:
8:
9:
```

Go to Step 19.

- Press the <Previous Screen> key to return to the first status screen.

  From this screen you can define tests for the other Section.

  Repeat Steps 2 to 14.

**NOTE:** Sections can be started individually, as in Step 18 above. They can also be started together from the Main Menu. The only difference is in defining the user ID. Sections started together will use the same user ID; those started individually can use different user ID.

Step 19

Press a digit on the <Number Key> pad corresponding to the user ID assigned to this Section.

The following message appears:

```
Starting Section please wait
```

---

* If only one user ID was defined, that ID appears on the assay report; if no user IDs were defined, no ID is included on the assay report.

In a moment the first status screen appears with the status of the started Section now being "Bar Code." This indicates the run has started and the instrument is reading bar code data from the Reagent Strips.

Step 20

Press <Previous Screen> to return to the Main Menu.

## Assigning a Dilution Factor

Use this option to assign a dilution factor to an individual test. If, for example, a sample must be diluted to bring a quantitative result on scale, the mini VIDAS automatically adjusts the result for the factor you entered.

Report printouts indicate when a dilution factor is being used. On-screen, you can verify if a dilution factor is being used by the presence of a boxed number, as in Position 4 in the figure below.

A dilution factor can be assigned or changed at any time before the completion of a run.

**NOTE:** Standards, controls, and Qualitative assays should not be diluted.

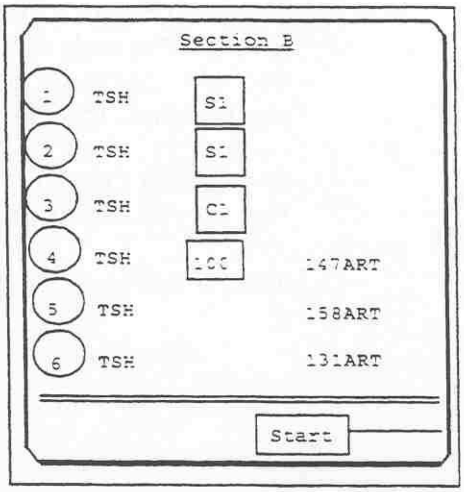
Step 1

Select `[Status Screen]` on the Main Menu.

Step 2

Select `[Section A]` or `[Section B]`, depending on which Section you plan to assign a dilution factor.

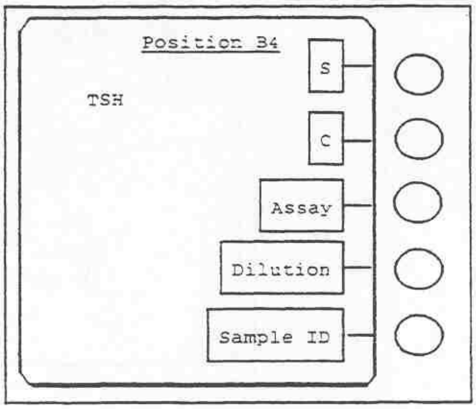
The following screen appears:



Step 3

Press the <Number Key> on the keypad corresponding to the Position where you want to assign a dilution factor.

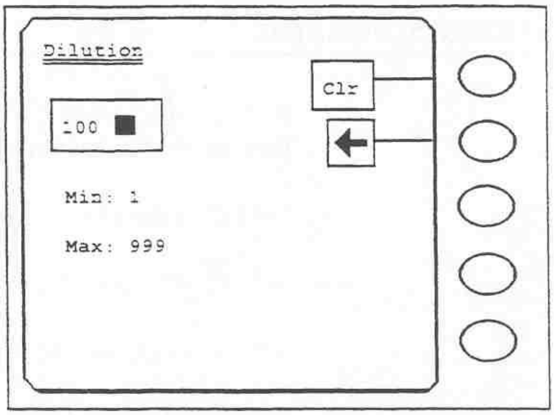
A screen similar to the following appears:


Position B4
TSH
S
C
Assay
Dilution
Sample ID

**NOTE:** If the Position contains an assay that should not be diluted, the `[Dilution]` selection in the screen above does not appear. Also, if you attempt to dilute a standard or a control, that designation is removed and the test becomes a normal assay.

Step 4 Select `[Dilution]`.

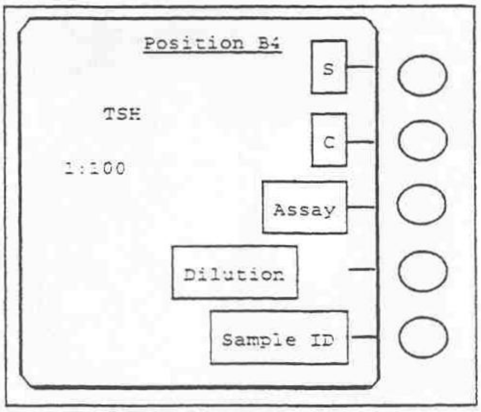
A screen similar to the following appears:


Dilution
100
Min: 1
Max: 999
Clr
←

Step 5 Enter a `[Dilution]` factor between 1 and 999.

Step 6 Press the <ENTER> key.

The screen returns to the Position screen with the new dilution factor displayed, similar to the following:


Position B4

TSH

1:100

Step 7 Step 7 has two options.

- Press the <Previous Screen> key to return to the Section Screen.

  Repeat Steps 3 through 6 to assign dilution factors to additional Positions in the Section.

- Press the <ENTER> key to return to the Main Menu.

## Listing Stored Standards

If you need to see the standards for a particular assay lot, perform the following procedure:

Step 1 Select `[Master Lot Menu]` on the Main Menu.

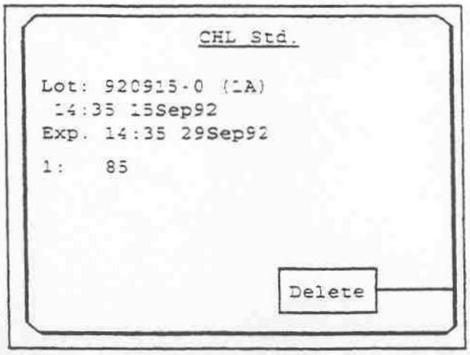
Step 2 Select `[List Stored Stds.]`.

An assay code list appears.

Step 3 Optional. Press the <DOWN> arrow key until the assay code you want appears.

Step 4 Select the [assay code].

A screen similar to the following appears:


CHL Std.

Lot: 920915-0 (1A)
14:35 15Sep92
Exp. 14:35 29Sep92
1:   85

Step 5

Step 5 has three options:

- Press <ENTER> to view additional standards (if any) for this assay type.

  **NOTE:** If there are additional standards, the display prompts you to indicate their presence.

Step 5, continued

- Press <Previous Screen> to return to the Utility Menu.
- Select `[Delete]` to delete the stored standard shown.

  The following prompt appears:

  ```
  Standard will be deleted.  Are
  you certain?
  ```

Step 6

Select `[Yes]` to delete the stored standard.

The program exits to the Utility Menu.

## Listing Master Lots

Use this procedure to display the master lots for a particular assay.

Step 1

Select `[Master Lot Menu]` on the Main Menu.

Step 2

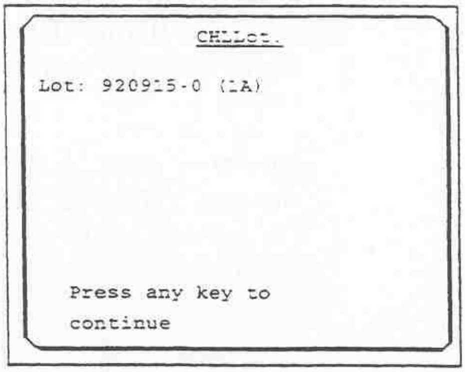
Select `[List Master Lots]`.

A list of assays appears for which master lot data exists.

Step 3

Select an `[assay code]` for which you want to display Master Lot Data.

A screen similar to the following appears:



```
CHLLot.

Lot: 920915-0 (1A)

Press any key to
continue
```

**NOTE:** If there is more than one lot having master lot data, a lot selection screen appears first.

| | |
|---|---|
| Step 4 | Press any key to return to the Assay Code List. |
| Step 5 | Step 5 has two options: |

- Select another `[assay code]` for which you want to display Master Lot data.

  Go to Step 4.
- Press the <ENTER> key to return to the Main Menu.

## Entering Master Lot Data

Many mini VIDAS assays require an additional step prior to running a standard. This step is the input of Master Lot Data. The data includes several types of parameters that the system needs to run an assay.

Master Lot Data can be entered into the system either manually via the keypad, or automatically via either

- the Master Lot Entry (MLE) Card, or
- the TOS sheet

one of which is included in every assay kit.

Master Lot Entry cards and TOS sheets contain machine readable bar codes. The Master Lot Entry card is read by the mini VIDAS bar code reader inside the instrument. The TOS sheet is read by a bar code wand.

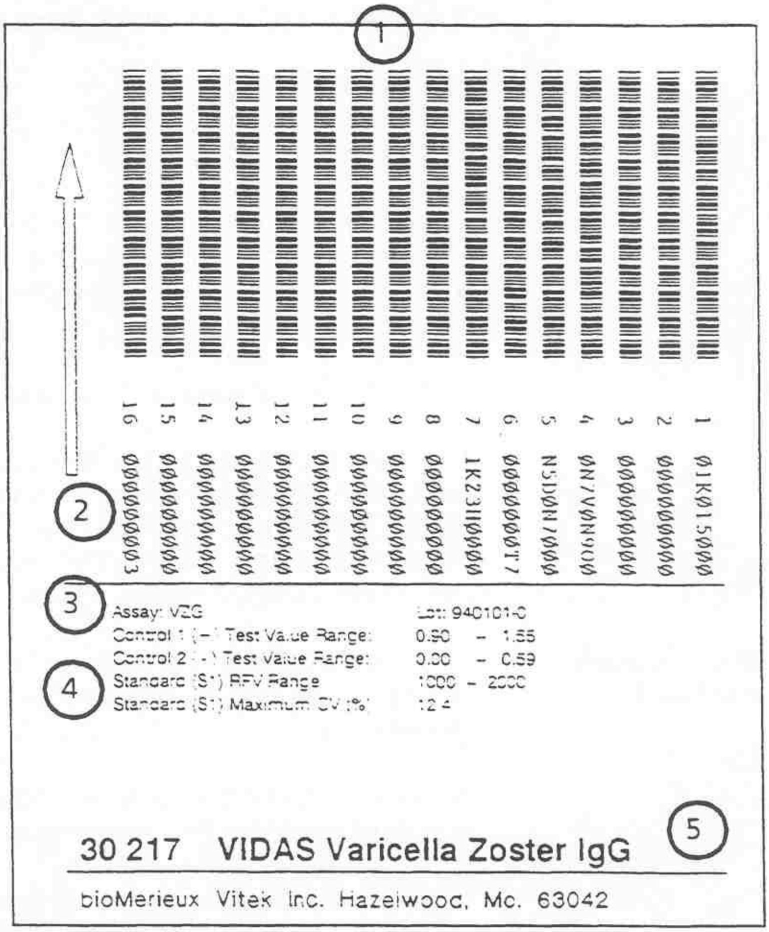
Manual entry of Master Lot Data is a backup capability to the automatic entry. The Master Lot Entry Card and TOS sheets both contain alphanumeric equivalents to the machine- readable bar codes.

Whether read by the instrument or entered manually, Master Lot Data is checked by the system for accuracy, using a check code that is part of the data entry.

## Automatic Entry via the Master Lot Entry (MLE) Card

Use this procedure to enter Master Lot Data from a Master Lot Entry (MLE) Card. The Master Lot Entry Card is placed into a specially designed holder and then inserted into a Section of the mini VIDAS Module. Note that the data is presented in two forms: machine-readable bar codes and alphanumerics. This allows for manual data entry or correction if the machine cannot read all of the bar codes.

Following is a sample card for a VZG assay kit.



1 01K015000
2 000000000
3 000000000
4 0N7V0N900
5 N5D0N7000
6 0000000T7
7 1K23II000
8 000000000
9 000000000
10 000000000
11 000000000
12 000000000
13 000000000
14 000000000
15 000000000
16 000000003

Assay: VZG Lot: 940101-0
Control 1 (+) Test Value Range: 0.90 - 1.55
Control 2 (-) Test Value Range: 0.00 - 0.59
Standard (S1) RFV Range 1000 - 2000
Standard (S1) Maximum CV (%) 12.4

30 217 VIDAS Varicella Zoster IgG

bioMerieux Vitek Inc. Hazelwood, Mo. 63042

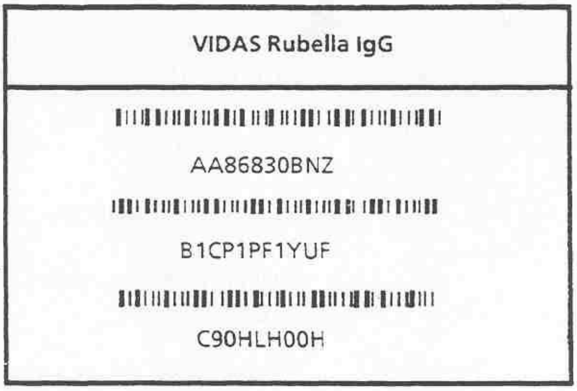
| Reference | Description |
|---|---|
| 1 | Machine-readable bar codes. These bar codes are read by the bar code reader in the mini VIDAS Module. |
| 2 | Alphanumeric codes. In case of a read error by the machine, these codes can be manually entered. |

| Reference, continued | Description |
|---|---|
| 3 | Assay code and lot number. The data contained on the card applies only to this assay and lot. |
| 4 | Controls and standards data. Shows the actual data being entered for controls and standards. |
| 5 | Full assay name. |
| Step 1 | Select `[Master Lot Menu]` on the Main Menu. |
| Step 2 | Select `[Read Master Lot]` on the Master Lot Menu.<br>The following selection options appear:<br>● `[Section A]`<br>● `[Section B]` |
| Step 3 | Place the Master Lot Data Card in the Reagent Strip tray of the Section you will use.<br>**NOTE:** The status of the selected Section must be "AVAIL.". |
| Step 4 | Select the appropriate [Section].<br>The mini VIDAS reads the bar coded data from the card. A message on the screen tells you the mini VIDAS is busy and prevents you from performing other operations. When the reading is completed, the screen returns to the Master Lot Menu. |
| Error Reading the Card | If the instrument is unable to read all the data on the card, the system beeps and an error message is generated.<br>Make sure the MLE Card is properly oriented in the tray and perform this procedure again.<br>If the instrument again fails to read the data, perform the manual data entry procedure, found later in this section. |

## Data Entry via the TOS Sheet

Use this procedure to enter Master Lot Data from a TOS sheet. This one procedure covers both manual data entry and automatic data entry via an optional bar code wand.

The figure below shows a portion of a TOS Sheet containing the machine readable bar codes and their alphanumeric equivalents.



**VIDAS Rubella IgG**

AA86830BNZ

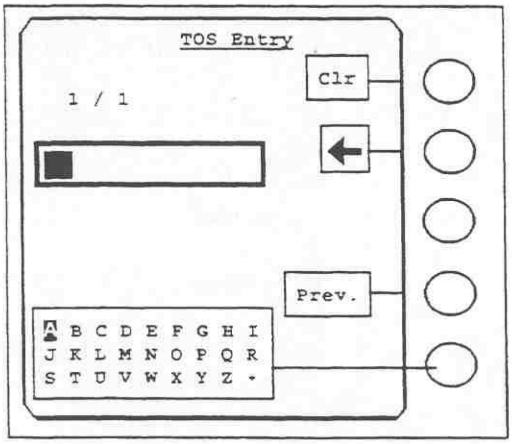
B1CP1PF1YUF

C90HLH00H

Step 1 Select `[Master Lot Menu]` on the Main Menu.

Step 2 Select `[Manual TOS Sheet Entry]` on the Master Lot Menu.

The TOS Entry screen appears:



Note the numbers "1 / 1." This is a system to count the bar codes as you enter them. The first number is the bar code being entered. The second number is the total number of bar codes entered. This number starts at "1" because the number of bar codes varies for different assays.

Step 3

Enter the correct bar code as follows:

- **For bar code wand entry:**

  Pass the wand over the machine readable bar code until the entry appears in the cursor box.

  Go to Step 4.

- **For manual entry:**
  - Use the appropriate <Number Key> to enter digits.
  - For letters, press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box, then select the [character box].

The numbers and letters appear in the box as you enter them. Continue this for all the characters in the bar code.

Use these functions as needed:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor
- `[Prev.]`* to go back to the previous bar code
- <ENTER> to input a completed bar code and to continue to the next bar code

Step 4

Press <Previous Screen> when the bar code entry is complete.

The message

```
Processing master lot data

Please wait
```

is displayed, indicating that the system is checking the bar code entries.

- If the entries are correct, the display returns to the Master Lot Menu; **you have completed this procedure.**

---

* Do not confuse this `[Prev.]` key that is on the display, with the <Previous Screen> key on the keypad.

- If one or more of the entries is incorrect, the following prompt is displayed:

```
Master lot data still bad

Edit again?
```

Step 5 Select `[Yes]` to return to the TOS Entry screen.

Compare the first bar code to the TOS sheet.

Step 6 Step 6 has two options:

- Correct the bar code if it does not match the TOS sheet.

  Go to Step 3.

- Press <ENTER> to display the next bar code.

Step 7 Go to Step 4.

## Manual Master Lot Data Entry

There are two cases in which you might enter data manually:

- To correct bar codes read incorrectly by the system
- To use manual entry as the first method

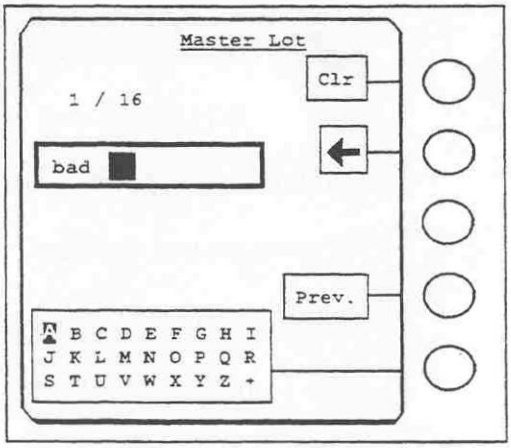
Each case has its own procedure, as shown below.

Case 1 Manual entry is used to correct bar codes misread by the system

Step 1 Select `[Master Lot Menu]` on the Main Menu.

Step 2 Select `[Manual Master Lot Entry]` on the Master Lot Menu.

The following screen appears:



Master Lot

1 / 16

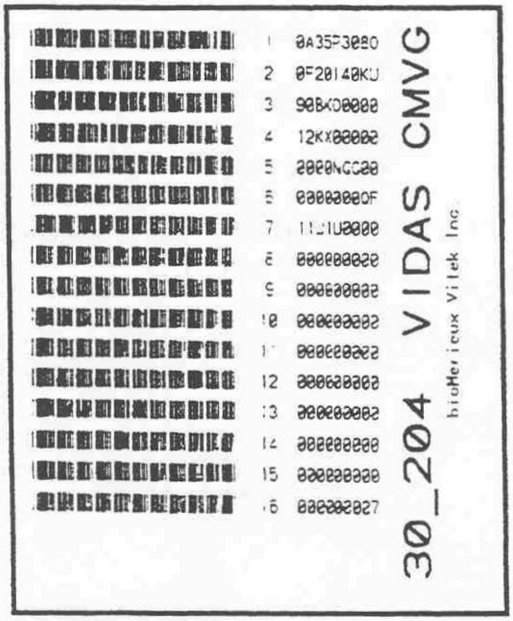
bad

Clr
←
Prev.
A B C D E F G H I
J K L M N O P Q R
S T U V W X Y Z +

Note the numbers "1 / 16" on the screen. They indicate that there is a total of 16 bar codes on the Master Lot Data Card, and, in the example shown, bar code #1 is bad.

Step 3 Select `[Clr]` to clear the bar code window of the message "bad."

Step 4 Find the appropriate bar code on the Master Lot Data Card. The figure below shows a portion of a sample card with the 16 machine- readable bar codes and matching alphanumeric strings.



30_204 VIDAS CMVG
bioMerieux Vitek Inc

Step 5 Enter the correct bar code as follows:

- Use the appropriate <Number Key> to enter digits.

- For letters, press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box, then select the [character box].

The numbers and letters appear in the box as you enter them. Continue this for all nine characters in the bar code.

Use these functions as necessary:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor
- `[Prev.]` to go back to the previous bar code

Step 6

Press <Previous Screen> when the bar code entry is complete.

The system checks the bar code.

- If the bar code was entered correctly and there are no other errors, the display exits to the Master Lot Menu and you have completed the Master Lot Data entry.
- If you entered the bar code incorrectly, or if other bar codes need to be corrected, the following prompt appears:

```
Master lot info data bad. Edit
again?
```

Step 7

Select `[Yes]` to continue the entry process.

The manual bar code entry screen appears again. Note the number indicating the bar code number, 1 to 16, and proceed by repeating Steps 3 to 6.

Case 2: Manual entry is the first method

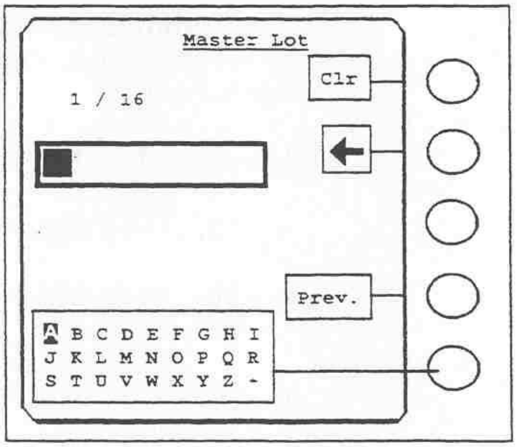
Step 1

Select `[Master Lot Menu]` on the Main Menu.

Step 2

Select `[Manual Master Lot Entry]` on the Master Lot Menu.

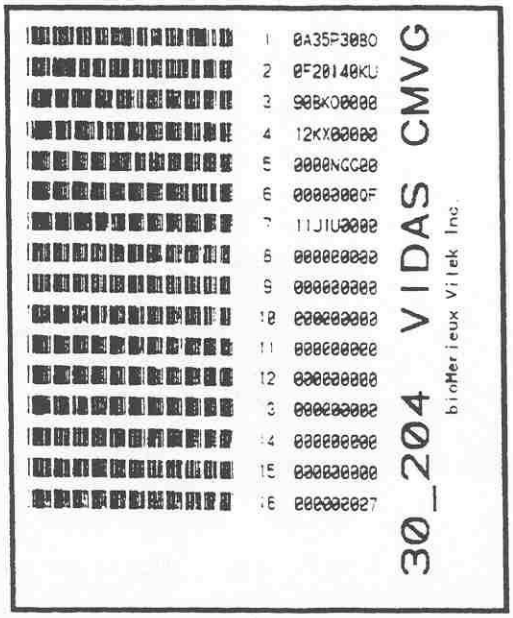
The following screen appears:



Note the numbers "1 / 16" on the screen. They indicate that there is a total of 16 bar codes on the Master Lot Data Card, and, in the example shown, you are entering bar code #1.

Step 3

Find the appropriate bar code on the Master Lot Data Card. The figure below shows a portion of a sample card with the 16 machine- readable bar codes and matching alphanumeric strings.



1 0A35P3080
2 0F20140KU
3 90BK00000
4 12KX00000
5 0000NGC00
6 00000000F
7 11JIU0000
8 000000000
9 000000000
10 000000000
11 000000000
12 000000000
13 000000000
14 000000000
15 000000000
16 000000027

30_204 VIDAS CMVG

bioMerieux Vitek Inc.

Step 4

Enter the correct bar code as follows:

- Use the appropriate <Number Key> to enter digits.

- For letters, press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box, then select the [character box].

The numbers and letters appear in the box as you enter them. Continue this for all nine characters in the bar code.

Use these functions as needed:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor
- `[Prev.]`* to go back to the previous bar code

Step 5

Press <Previous Screen> when the bar code entry is complete.

The system checks the bar code.

- If you entered the bar code incorrectly, or if there are additional bar codes to correct, the following prompt appears:

  ```
  Master lot info data bad. Edit
  again?
  ```

  Go to Step 6.

- If bar code #16 is entered correctly, the display returns to the Master Lot Menu. Entry of this Master Lot Data is complete.

Step 6

Select `[Yes]` to continue the entry process.

The manual bar code entry screen appears again. Note the number indicating the bar code number, 1 to 16, and proceed by repeating Steps 3 to 5.

---

* Do not confuse this `[Prev.]` key that is on the display, with the <Previous Screen> key on the keypad.

## Halting a Section

Use this procedure to stop the processing of one or both Sections.

Step 1

Select `[Utility Menu]` on the Main Menu.

**NOTE:** A halt option is also available on the first status screen, accessed via the `[Status Screen]` selection on the Main Menu. This halt option is available only while a Section is running.

Step 2

Select `[Halt Section]` on the Utility Menu.

The following selections appear:

- `[Section A]`
- `[Section B]`

Step 3

Select one of the [sections] to halt.

The following selections appear:

- `[Halt (clear setup)]`
- `[Halt (retain setup)]`

Step 4

Step 4 has two options:

- Select the "clear setup" option to halt the Section and to erase the tests defined in the Positions. Use this option when the tests will not be run again.
- Select the "retain setup" option to halt the Section and retain the tests defined in the Positions. Use this option when the tests will be run again.

The Utility Menu appears again.

Step 5

Press <Previous Screen> to return to the Main Menu.

# 5. Results and Reports

## Introduction

This chapter covers two aspects of the data produced by the mini VIDAS: how it is analyzed by the onboard computer, and how the results are reported.

Topics in the chapter include

- Analysis Methods 5-2
  - Qualitative and Semi-Quantitative Single Reagent Strips 5-3
  - Qualitative Dual Reagent Strips 5-4
  - Quantitative Assays 5-5
- The Assay Report 5-6
  - Qualitative Single Reagent Strips 5-7
  - Qualitative Dual Reagent Strips 5-8
  - Quantitative Assays 5-8
- Assay Report Errors 5-9
- Reprinting an Assay Report 5-10
- Validating LIS Results 5-13
- Printing the mini VIDAS Assay List 5-15
- Printing the FTI Report 5-16

## Analysis Methods

The mini VIDAS uses several different methods to calculate results. There are three basic categories of analysis methods:

- **Patient to Standard.** A comparison of the Relative Fluorescence Value (RFV) of the test sample to that of a standard. This method is used in Single Reagent Strip qualitative, and most semi-quantitative assays.
- **Patient to Reference.** A comparison of the RFV of the test sample to that of a reference blank. This method is used in Dual Reagent Strip qualitative assays.
- **Curve Fitting Equations.** The RFV of a test sample is mathematically placed on a Calibration Curve. This method is used for all quantitative, and some semi-quantitative assays.

### Terminology

The following terms are used in the discussion of analysis methods:

- **Background.** The reading taken on the optical cuvette during the preprocessing phase of a run. It represents the fluorescence of substrate alone.
- **RFV** - Relative Fluorescence Value. This is the fluorescence reading of a Reagent Strip minus the Background.
- **Reference.** The second strip of a Dual Reagent Strip pair. It lacks the reaction ingredient that forms a fluorescent product.
- **Standard.** For qualitative and semi-quantitative assays, this is a solution of known RFV against which the RFV of a test sample can be compared. For a quantitative assay, it is a solution with a known concentration of analyte that is used to calibrate a standard curve.
- **Test Value.** In qualitative and semi-quantitative assays, it is the quantity calculated according to the analysis method. The Test Value is compared to a set of thresholds to generate the assay result.

- **Threshold.** Experimentally determined Test Values for qualitative and semi-quantitative assays that translate the Test Value into a clinically significant Result.

  Results used in the system are

  - Positive. There is a clinically significant level of analyte in the test sample.
  - Negative. A clinically significant level of analyte is not present in the test sample.
  - Equivocal. This result falls in the zone between the Positive and Negative. The Test Value obtained is close to both Positive and Negative results. Equivocal results suggest, therefore, that a test be rerun.

## Qualitative and Semi-Quantitative Assays: Single Reagent Strips

Two analysis methods are used for Single Reagent Strip qualitative assays: the P/S method and the P-S method. In these methods, the "P" stands for the RFV of the test sample and the "S" stands for the RFV of a standard.

### Assay Calibration

Single Reagent Strip assays are calibrated using a standard supplied with the assay kit. A standard should be run the first time the assay kit lot is used. If replicate standards are run, their values are averaged. The standard result obtained can be used for a programmed period of days. After that, the software automatically expires the standard, requiring that you run another from the same lot.

### P/S Method

For assays that use the P/S method, the test value is calculated from the ratio of the sample RFV to that of the standard RFV.

Example

RFV (sample) = 2158
RFV (standard) = 2177
Test Value = 2158/2177 = 0.99

### P-S Method

For assays that use the P-S method, the test value is calculated from the difference between the sample RFV and the standard RFV.

Example

RFV (sample) = 1774
RFV (standard) = 1689
Test Value = 1774 - 1689 = 85

**Assay Result**

In both the P/S and P-S methods, the result of the assay is determined by comparing the test value to a set of preprogrammed thresholds. For every assay type, there is a high and low threshold value. The assay result is interpreted from the test value as follows:

| If the test value is | the result is |
|---|---|
| ≥ high threshold | Positive |
| < high and ≥ low threshold | Equivocal |
| < low threshold | Negative |

## Qualitative Assays: Dual Reagent Strips

Two analysis methods are used for Dual Reagent Strip qualitative assays: the P/N method and the P-N method. In these methods, the "P" stands for the RFV of the test sample and the "N" stands for the RFV of a reference.

**Assay Calibration**

Dual Reagent Strip assays do not require separate calibration standards. Instead, the reference strip serves the same purpose.

**P/N Method**

For assays that use the P/N method, the test value is calculated from the ratio of the sample RFV to that of the reference RFV.

Example
RFV (sample) = 2158
RFV (reference) = 2177
Test Value = 2158/2177 = 0.99

**P-N Method**

For assays that use the P-N method, the test value is calculated from the difference between the sample RFV and the reference RFV.

Example
RFV (sample) = 1774
RFV (reference) = 1689
Test Value = 1774 - 1689 = 85

**Assay Result**

In both the P/N and P-N methods, the result of the assay is determined by comparing the test value to a set of preprogrammed thresholds. For every assay type, there is a high and low threshold value. The assay result is interpreted from the test value as follows:

| If the test value is | the result is |
|---|---|
| ≥ high threshold | Positive. |
| < high and ≥ low threshold | Equivocal |
| < low threshold | Negative |

## Quantitative Assays

Quantitative mini VIDAS assays use a Calibration Curve to determine analyte concentrations in test samples. Three basic steps are required to run quantitative assays:

1. Enter the data for the Calibration Curve into the system. The data, called the Master Lot Data, is supplied with the assay kit and is applicable for all tests run using this particular assay kit lot.

2. Calibrate the Calibration Curve using the one or two calibration standards supplied with the assay kit. This adjusts the Calibration Curve to your mini VIDAS.

   **NOTE:** Although standards can be run after test samples have completed, it is recommended that they be run either before or with test samples from the same assay kit lot.

   **NOTE:** If an assay has two calibrators, both must be run at the same time.

3. Run the test samples.

**Calibration Curve**

For every quantitative assay, a set of standards is run in our laboratories from which we plot concentration vs. fluorescence. To ensure accuracy, the set of standards is prepared from the serial dilution of a standard derived, if possible, from the World Health Organization. The results of these assays are used to construct a curve. Then, using curve fitting methods, an equation for the curve is determined. The curve is called the calibration curve for the assay, and the equation is the tool the mini VIDAS uses to calculate results.

**Master Lot Data**

Each assay kit is accompanied by a Master Lot Data card. When the data from this card is entered, you are entering the calibration curve for the assay.

**Recalibration**

The final calibration step for a quantitative assay is to run a standard that is supplied with the assay kit. Since the standard is a known quantity (it is entered with the master lot data), the software can make any final adjustments to the calibration curve that may be needed. Since the characteristics of the reagents in an assay kit may vary over time, the mini VIDAS software automatically expires a standard after a programmed number of days. To recalibrate, you run another standard from the same assay kit lot.

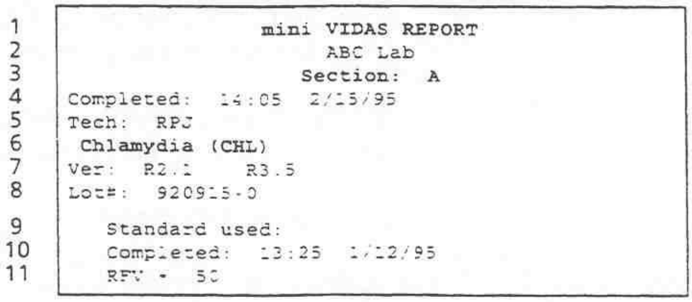
## The Assay Report

When the run for a Section is completed, the mini VIDAS automatically prints an assay report. The report is printed on the internal printer, by default, or on the optional external printer, depending on how the appropriate configuration option is set.

All assay reports are similar, but not identical. Slight differences occur, depending on the assay type. The following subsections describe parts of the report.

**Report Header**

The figure below shows a sample of a report header that contains information common to all reports[1].



```
1                    mini VIDAS REPORT
2                         ABC Lab
3                       Section:  A
4   Completed:  14:05  2/15/95
5   Tech:  RPJ
6    Chlamydia (CHL)
7   Ver:  R2.1    R3.5
8   Lot#:  920915-0

9      Standard used:
10     Completed:  13:25  1/12/95
11     RFV =  50
```

**NOTE:** The line numbers in the figure do not appear on a real report.

| Line | Description |
|---|---|
| 1 | The report title, mini VIDAS Report |
| 2 | The custom report header characters you can enter in the appropriate configuration option |
| 3 | The identity of the Section, A or B |
| 4 | Date and time the assay completed |

---

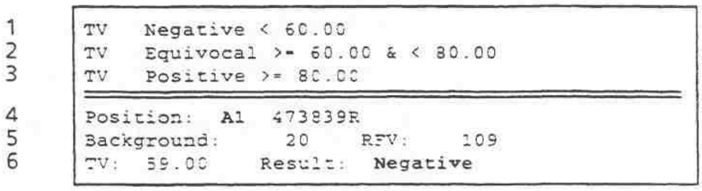
[1] Lines 9 to 11 do not appear on reports for Dual Reagent Strip assays.

| | |
|---|---|
| 5 | Technologist ID, from the appropriate configuration option |
| 6 | Name (and code) of the assay |
| 7 | The revision level of the mini VIDAS system software (SW) and the assay protocol (AD) |
| 8 | Assay kit lot number |
| 9 | Information on the standard used, including |
| 10 | Date and time the standard was run |
| 11 | RFV of the standard |

**NOTE:** Lines 9, 10, and 11 do not appear on reports for Dual Reagent Strip Assays.

## Qualitative Assay (Single Reagent Strip)

The figure below shows the parts of the report that appear after the header information.



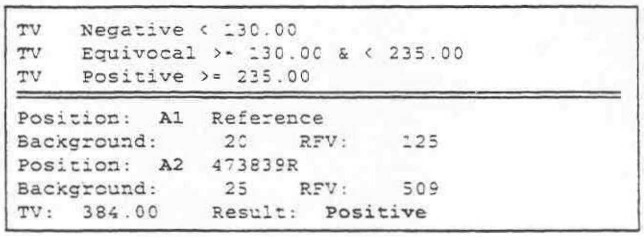
```
1   TV   Negative < 60.00
2   TV   Equivocal >= 60.00 & < 80.00
3   TV   Positive >= 80.00
    ==========================================
4   Position:  A1   473839R
5   Background:      20    RFV:     109
6   TV:  59.00     Result:  Negative
```

| Line | Description |
|---|---|
| 1, 2, & 3 | Thresholds.The numbers given are the Test Values (TV) for the three interpretive results, Negative, Equivocal, and Positive. |
| 4 | Position identifier. Identifies the Position within the Section. When appropriate, this field is also used for the sample ID of the test sample, or to identify standards or controls. |
| 5 | Background reading and the RFV of the test sample. |
| 6 | Test Value and interpretive result of the test sample. |

**NOTE:** Lines 4 to 6 are repeated on the report for each Position containing an assay strip.

## Qualitative Assay (Dual Reagent Strip)

The figure below shows the parts of the report that appear after the header information.



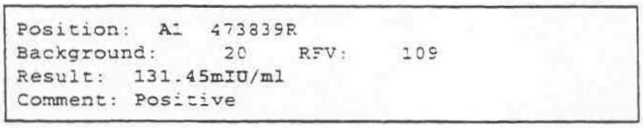
```
1  TV   Negative < 130.00
2  TV   Equivocal >= 130.00 & < 235.00
3  TV   Positive >= 235.00
   ==========================================
4  Position:  A1  Reference
5  Background:      20    RFV:     125
6  Position:  A2  473839R
7  Background:      25    RFV:     509
8  TV:  384.00     Result:  Positive
```

| Line | Description |
|---|---|
| 1, 2, & 3 | Thresholds. The numbers given are the Test Values (TV) for the three interpretive results, Negative, Equivocal, and Positive. |
| 4 | Position identifier. Identifies the Position within the Section. |
| 5 | Background reading and RFV of the reference strip. |
| 6 | Position identifier for the test strip and the sample ID of the test sample. |
| 7 | Background reading and RFV of the test strip. |
| 8 | Test Value and interpretive result of the test sample. |

**NOTE:** Lines 4 to 8 are repeated on the report for each Position containing an assay strip.

## Quantitative Assays

The following figure shows the parts of the report that appear after the header information.



```
1  Position:  A1  473839R
2  Background:      20    RFV:     109
3  Result:  131.45mIU/ml
4  Comment: Positive
```

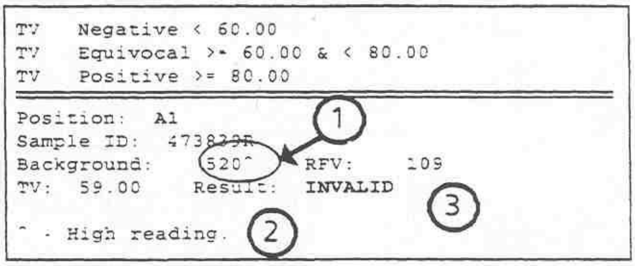
| Line | Description |
|---|---|
| 1 | Position identifier. Identifies the Position within the Section. |

| | |
|---|---|
| 2 | Background reading and the RFV of the test sample. |
| 3 | Quantitative test result.<br>**NOTE:** Lines 1 to 3 are repeated on the report for each Position containing an assay strip. |
| 4 | An optional comment field, seen only on certain reports. |

## Assay Report Errors

The mini VIDAS assay report is designed to display error messages whenever a result does not conform to the internal controls that are programmed for each assay.

On the report, any values found to be outside control ranges are footnoted. An error message is then printed at the bottom of the report. Following is an example.



```
TV   Negative < 60.00
TV   Equivocal >= 60.00 & < 80.00
TV   Positive >= 80.00
================================================
Position:  A1
Sample ID:  473839R
Background:     520^   RFV:     109
TV:  59.00     Result:  INVALID

^ - High reading.
```

| Reference | Description |
|---|---|
| 1 | Footnoted value. Note the "^" symbol next to the value. Different symbols are used for different error messages. |
| 2 | Footnote and error message. In this case, the error message is "High reading." |
| 3 | The test result has been flagged as "INVALID" due to the nature of the error. |

★ See Chapter 7 for a listing of the error messages.

## Reprinting an Assay Report

mini VIDAS can store up to eight results. They can be divided between the two Sections in any combination. For example, all eight results could be from one Section, or there could be four results from each Section. The total, however, can not exceed eight.

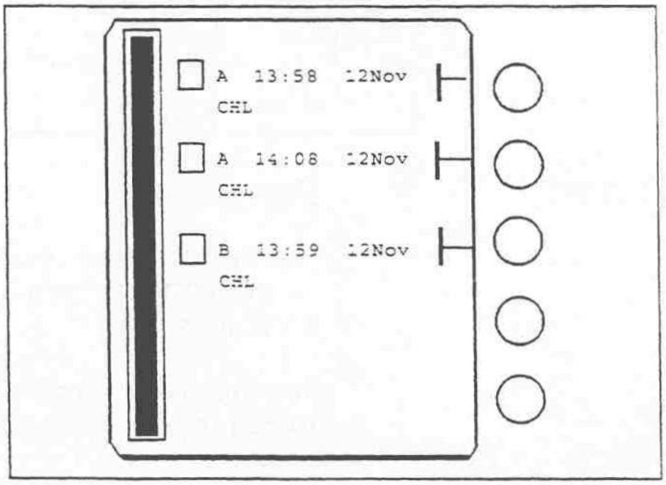
The storage system works on a "First In, First Out" basis. This means that the last eight results produced are the ones that are stored. When the ninth result is created and stored, the first result to be stored is deleted.

**NOTE:** Only those tests stored in the mini VIDAS memory are available for reprinting. If the system is turned off, stored results are no longer available.

Step 1 Select `[Results Menu]` from the Main Menu.

Step 2 Select `[Reprint Results]` on the Results Menu.

A screen similar to the following appears:



☐ A 13:58 12Nov
CHL

☐ A 14:08 12Nov
CHL

☐ B 13:59 12Nov
CHL

Step 3 Select one or more Sections to reprint.

An `[X]` appears in the box for the selected Section(s).

Step 4

Press the <ENTER> key to print your selection(s).

The following prompt appears:

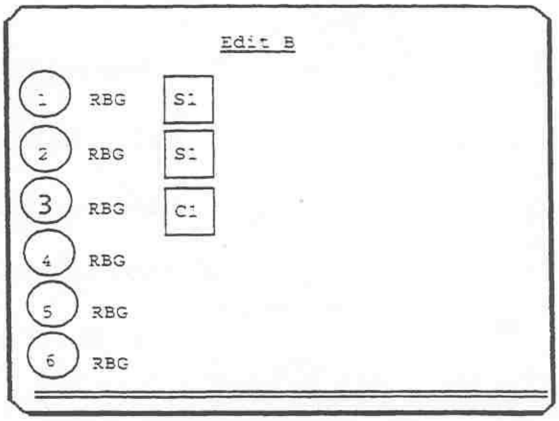
```
Edit the data before reprinting?
```

**NOTE:** Results can be edited only to apply the most recently stored standard. Once the new standard is applied, it is used every time the result is reprinted. It is **NOT** possible to revert to the original standard. All results in a Section that are from the same assay and lot are affected.

Step 5

Step 5 has two options:

- Select `[Yes]` to edit one or more Positions in a Section. The following screen appears:



  Go to Step 6.

- Select `[No]` to reprint the selected Section(s).

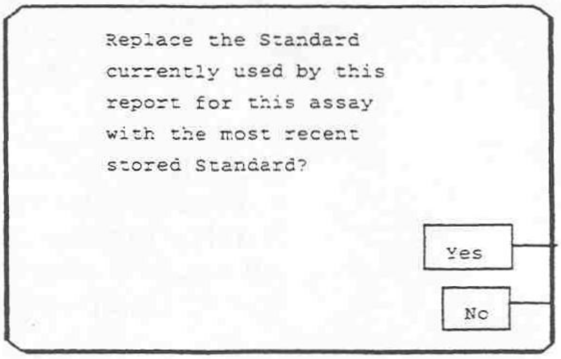
  The display returns to the Results Menu.

  Go to Step 8.

Step 6

Press a <Number Key>, 1 to 6, to indicate the Position you want to edit.

A screen similar to the following appears:



```
Replace the Standard
currently used by this
report for this assay
with the most recent
stored Standard?
```

Step 7

Step 7 has two options:

- Select `[Yes]` to replace the standard currently used.

  The following message is displayed:

  ```
  Retrieving most recent Standard

  Please wait....
  ```

  followed by the message:

  ```
  Standard replaced

  Press any key to continue
  ```

The screen returns to the Section screen for further editing.

When all Positions in a Section have been edited, press the <ENTER> key to edit the next Section.

Go to Step 6.

When all Sections have been printed, the screen returns to the Results Menu.

- Select `[No]` to not replace the standard currently used and print the report.

The screen returns to the next Section for editing.

Go to Step 6.

When all Sections have been printed, the screen returns to the Results Menu.

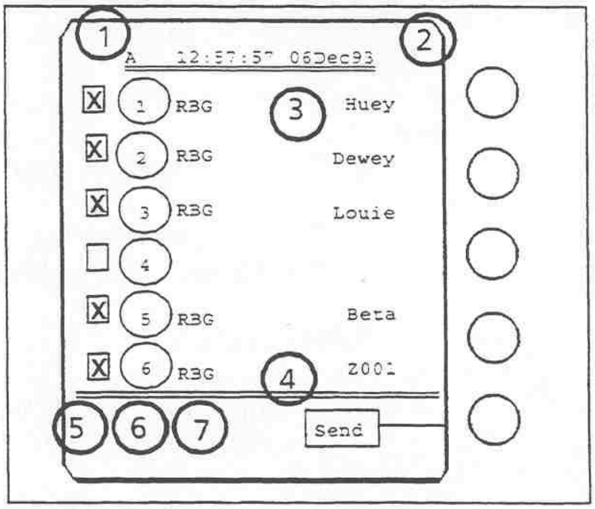
| | |
|---|---|
| Step 8 | Press the <ENTER> key to return to the Main Menu. |

## Validating LIS Results

Use this procedure to Validate results before sending to LIS.

| | |
|---|---|
| Step1 | Select `[Results Menu]` from the Main Menu. |
| Step 2 | Select `[Validate LIS results]` on the Results Menu. |

A screen similar to the following appears.



| Reference | Description |
|---|---|
| 1 | Section number. This label shows you are looking at assays that were run in Section A. |
| 2 | Time stamp. This label shows you the date and time the results were completed. |
| 3 | Sample ID. This column lists the Sample IDs. |
| 4 | Send. A selection option to upload the results to the LIS queue. |
| 5 | Check boxes. When an `[X]` appears in these boxes the Positions are validated for LIS upload. The `[X]` is the default except in the following cases: |

- expired reagent kit lot
- expired calibration standard

Reference, continued Description

- last control(s) run were out of range
- result based on a singlicate standard

When a result is determined to be invalid, it is shown on the screen but does not include a check box. Select or deselect the Position by pressing the <Number> key corresponding to the Position number.

6 Position numbers. These numbers identify the six Positions in the Section.

7 Assay code. These codes appear as tests are assigned to the Section.

Step 3 Step 3 has four options.

- Select `[Send]` to upload the results to the LIS.

  The screen will advance to the next Section's results awaiting validation, if any.

Repeat Step 3.

When all of the results have been validated, the screen returns to the Results Menu.

- Select a Position to withhold from uploading to the LIS by pressing the <Number> key that corresponds to that Position.

  The `[X]` will be removed from that box indicating that the test result will not be uploaded to LIS.

Repeat Step 3.

- Press the <ENTER> key to delete the remaining non-validated LIS upload data.

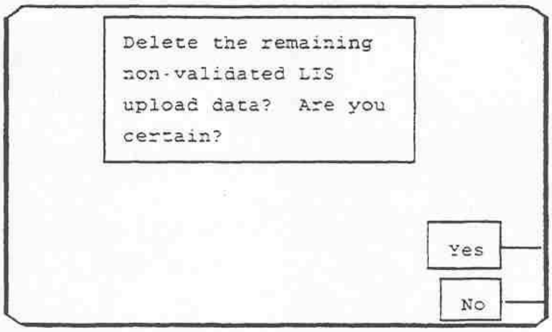
  The following screen appears:

Go to Step 4

- Press the <Previous Screen> key to abort the validation.

  The following message appears:

```
Validation aborted.  Current
Section's results NOT validated.
```



Delete the remaining non-validated LIS upload data? Are you certain?

The screen returns to the Results Menu.

**NOTE:** There may be only 8 Section's results awaiting validation in the validation queue. If this queue is full, a warning message will appear when you start additional assays. The message will warn you that the assay you are about to start will not be placed in the LIS validation queue unless you validate some results. However, the results will still be printed.

Step 4

Step 4 has two options.

- Select `[Yes]` to delete the remaining non-validated LIS upload data.

  The screen returns to the Results Menu.

- Select `[No]` to not delete the remaining non-validated LIS upload data.

  The screen will advance to the next Section's results awaiting validation, if any.

Go to Step 3.

When all of the results have been validated, the screen returns to the Results Menu.

Step 5

Press the <ENTER> key to return to the Main Menu.

## Printing the mini VIDAS Assay List

Use this procedure to print a list of the mini VIDAS assays that have master lot data loaded on your system. The assay list includes the complete name of each assay and its assay code. Assays on the list are grouped by compatible protocol.

Step 1

Select `[Results Menu]` from the Main Menu.

Step 2

Select `[Print Assay List]` on the Results Menu.

The following message appears for a moment.

```
Constructing assay list
printout.

Please wait
```

The assay list then begins to print and the display returns to the Results menu.

A portion of an assay list printout appears below. Note that the assays are grouped by compatible protocols.

```
          mini VIDAS Assay List
==========================================

LH    (AQ)  LH
FSH   (AR)  FSH
E2    (AS)  Estradiol
------------------------------------------
HCG   (C7)  HCG
FER   (C6)  Ferritine
------------------------------------------
TSH   (AK)  TSH
------------------------------------------
CMVG  (CA)  CMV IgG
RBG   (CN)  Rubella IgG
TXG   (C8)  Toxoplasma gondii IgG
TXM   (CC)  TOXO IgM
------------------------------------------
VZG   (1K)  Varicella-Zoster IgG
MSG   (1D)  Measles IgG
```

## Printing the FTI Report

Use this procedure to print an FTI report. This procedure may also be used to reprint an FTI report.

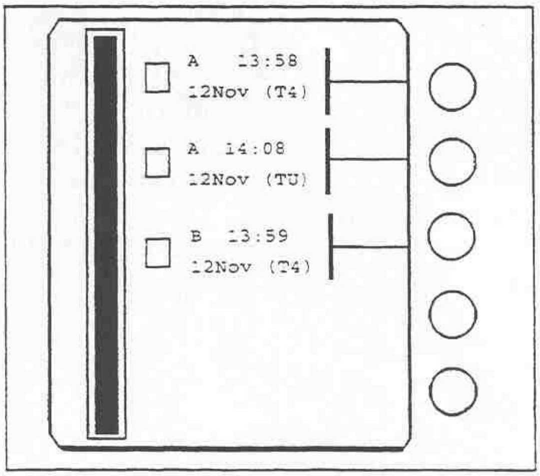
Step 1

Select `[Results Menu]` from the Main Menu.

Step 2

Select `[Print FTI Report]` on the Results Menu.

A screen similar to the following appears:



Step 3 Select one T4 and one TU assay.

An `[X]` appears in the box of the selected assays.

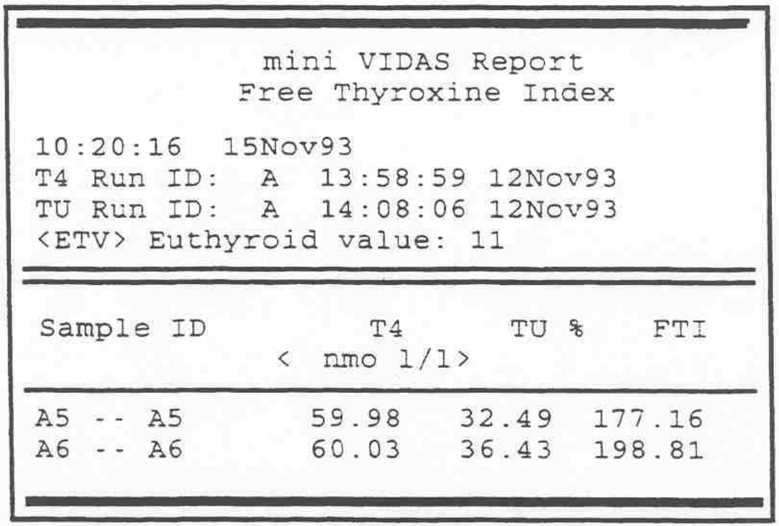
Step 4 Press the <ENTER> key to print the report.

The following message appears:

```
Creating FTI report.....
```

The display returns to the Results Menu before the report prints.

A report similar to the following is printed.



```
              mini VIDAS Report
            Free Thyroxine Index

10:20:16  15Nov93
T4 Run ID:  A  13:58:59 12Nov93
TU Run ID:  A  14:08:06 12Nov93
<ETV> Euthyroid value: 11

Sample ID           T4       TU %    FTI
                < nmo l/l>

A5 -- A5          59.98    32.49   177.16
A6 -- A6          60.03    36.43   198.81
```

FTI Report

NOTE: It is possible that the memory needed to create the report may be unavailable. In this case, you will be given a message to this effect and you will need to try again later when the memory has been freed. This can occur if an attempt is made to print two FTI reports in rapid sequence , or if an assay list is being printed, etc.

Step 5

Press the <ENTER> key to return to the Main Menu.

# 6. Miscellaneous Operations

## Introduction

This chapter contains a number of procedures that have been segregated from the other more frequently performed procedures shown in Chapters 3 to 5.

Following are the procedures in this chapter:

- Taking a Section Off Line 6-3
- Changing Factory Settings 6-3
  - Display Contrast 6-4
  - Keyclick Volume 6-5
  - Beep Volume 6-6
  - Error Beep Volume 6-7
  - Enabling Display Blinking 6-9
  - Selecting a Language 6-10
- Testing the mini VIDAS Instrument 6-11
  - Display Test 6-13
  - Keypad Test 6-13
  - Printer Test 6-14
  - Audio Output Test 6-15
- Displaying the Software Version 6-15
- Printing the Software Version 6-16
- Displaying the Assay Version 6-16
- Printing the Assay Version 6-18
- Updating the mini VIDAS Software via the Memory Card 6-19
- Updating the mini VIDAS Software via the BAP Card 6-21

- Verifying the Memory Card Data 6-22
- Backing Up Configuration and Master Lot Data 6-23
- Restoring Configuration and Master Lot Data 6-23
- Shipping the mini VIDAS 6-24

## Taking a Section Off Line

Use this procedure to take a Section off line. An offline Section is not available for running assays.

**NOTE:** Use the same procedure to place an offline Section on line.

Step 1 Select `[Utility Menu]` on the Main Menu.

Step 2 Select `[On/Off line]`.

The following selections appear:

- `[Section A]`
- `[Section B]`

Step 3 Select one of the Sections to place off line.

The display returns to the Utility Menu.

**NOTE:** You can confirm the offline status of a Section by selecting `[Status Screen]` on the Main Menu. The first screen shows the status of each Section.

## Changing Factory Settings

The factory settings control various physical parameters that affect the keypad and display screen. This section contains the procedures needed to change these parameters from the values set by bioMérieux Vitek.

**NOTE:** We suggest that you use the system for several days before changing any of the settings. After that time, if you find that any settings do not meet your needs, make the necessary adjustments.

**Accessing the Factory Settings**

All of the factory-set parameters are found on the Configuration Menu. Each procedure in this section, therefore, begins with a selection on the Configuration Menu. Refer to the following diagram for accessing the Configuration Menu.

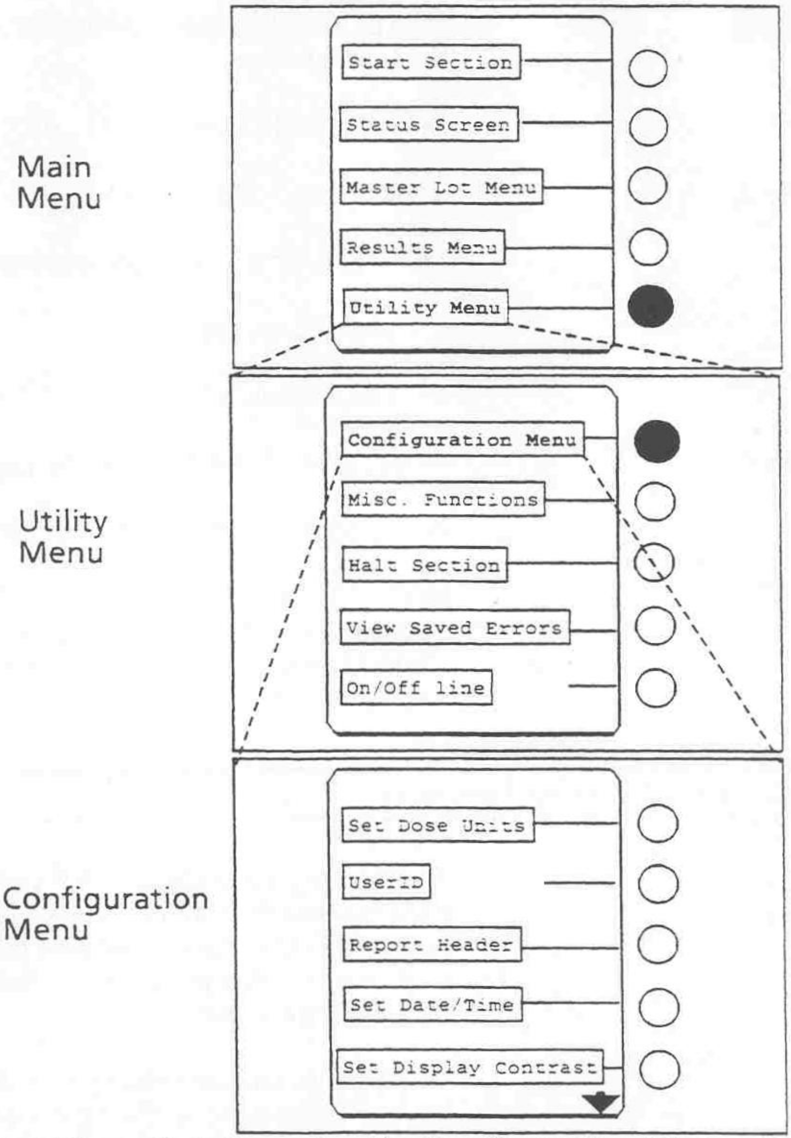

Main Menu
Start Section
Status Screen
Master Lot Menu
Results Menu
Utility Menu
Utility Menu
Configuration Menu
Misc. Functions
Halt Section
View Saved Errors
On/Off line
Configuration Menu
Set Dose Units
UserID
Report Header
Set Date/Time
Set Display Contrast

Figure 6–1 Accessing the Configuration Menu

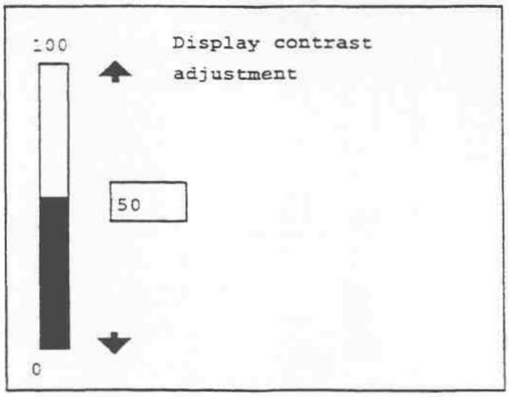
## Setting Display Contrast

The liquid crystal display on the mini VIDAS has a contrast adjustment to allow for proper viewing in different room lighting conditions. Use this procedure to adjust the contrast.

Step 1

Select `[Set Display Contrast].`

The following screen appears:



Step 2

Press the <UP> or <DOWN> arrow keys to adjust the display contrast.

The contrast bar and relative contrast level (number in the box) go up or down in response to your adjustments.

The actual display contrast also changes as you make the adjustments.

Step 3

Optional. Press the <UNDO> key to go back to the default setting.

Step 4

Press the <Previous Screen> key to exit to the Configuration Menu.

## Changing the Keyclick Volume

When you press any key on the keypad, there is an audible tone that confirms the keystroke. Use this procedure to change the volume of that tone.

Step 1

Press the <DOWN> arrow key twice to display the third page of the Configuration Menu.

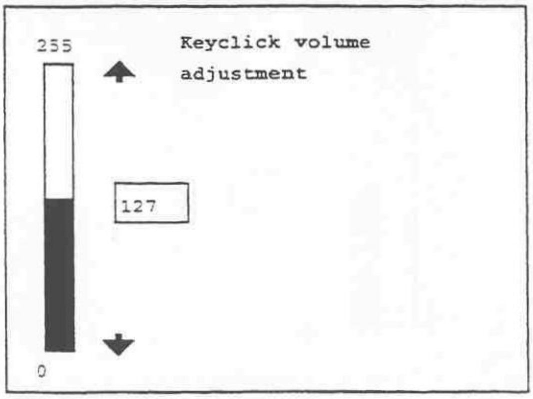
Step 2

Select `[Sound Menu]` on the Configuration Menu.

Step 3

Select `[Set Keyclick Volume]`.

The following screen appears:



Step 4

Press the <UP> or <DOWN> arrow keys to adjust the keyclick volume.

The volume bar and relative volume level (number in the box) go up or down in response to your adjustments.

Step 5

Optional. Press the <UNDO> key to go back to the default setting.

Step 6

Press the <Previous Screen> key to exit to the Sound Menu.

## Changing the Beep Volume

The beep is the tone you hear when you press a key that is inactive (it should not be pressed on the particular screen you are viewing). Use this procedure to change the volume of that tone.

Step 1

Press the <DOWN> arrow key twice to display the third page of the Configuration Menu.

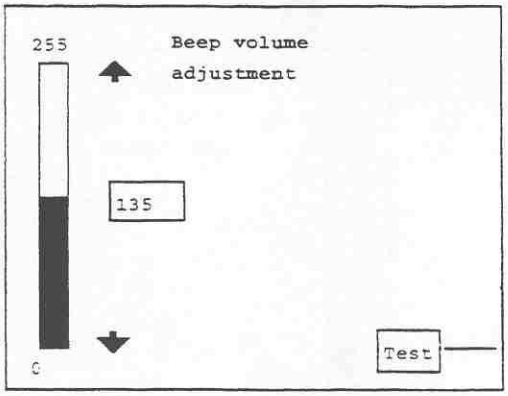
Step 2

Select `[Sound Menu]` on the Configuration Menu.

Step 3

Select `[Beep Volume]`.

The following screen appears:



Step 4

Press the <UP> or <DOWN> arrow keys to adjust the system beep volume.

The volume bar and relative volume level (number in the box) go up or down in response to your adjustments.

Step 5

Optional. Press the <UNDO> key to go back to the default setting.

Step 6

Optional. Select `[Test]` to hear the tone at the adjusted volume.

Step 7

Press the <Previous Screen> key to exit to the Sound Menu.

**Error Beeps**

When an error occurs, the mini VIDAS begins to beep. The beep grows louder over a 5 minute period. You can set the initial and final volume of this error beep.

## Setting Initial Error Volume

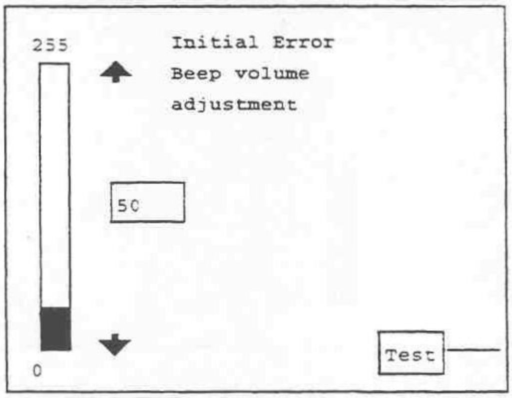
Step 1

Press the <DOWN> arrow key twice to display the third page of the Configuration Menu.

Step 2

Select `[Sound Menu]` on the Configuration Menu.

| | |
|---|---|
| Step 3 | Select `[Initial Error Volume]` on the Sound Menu.<br>The following screen appears: |



| | |
|---|---|
| Step 4 | Press the <UP> or <DOWN> arrow keys to adjust the initial error beep volume.<br>The volume bar and relative volume level (number in the box) go up or down in response to your adjustments. |
| Step 5 | Optional. Press the <UNDO> key to go back to the default setting. |
| Step 6 | Optional. Select `[Test]` to hear the tone at the adjusted volume. |
| Step 7 | Press the <Previous Screen> key to exit to the Sound Menu. |

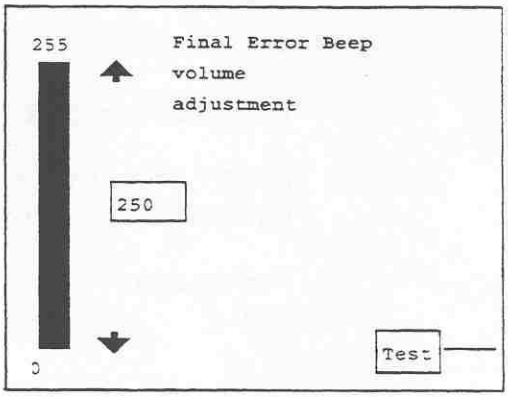
## Setting the Final Error Volume

| | |
|---|---|
| Step 1 | Press the <DOWN> arrow key twice to display the third page of the Configuration Menu. |
| Step 2 | Select `[Sound Menu]` on the Configuration Menu. |

Step 3

Select `[Final Error Volume]` on the Sound Menu.

The following screen appears:



Step 4

Press the <UP> or <DOWN> arrow keys to adjust the final error beep volume.

The volume bar and relative volume level (number in the box) go up or down in response to your adjustments.

Step 5

Optional. Select `[Test]` to hear the tone at the adjusted volume.

Step 6

Optional. Press the <UNDO> key to go back to the default setting.

Step 7

Press the <Previous Screen> key to exit to the Sound Menu.

## Enabling Display Blinking

While not a sound function per se, display blinking is associated with the error beep since it occurs only during an error condition.

Use this procedure to enable or disable the display blinking function. When enabled, it causes the display to blink (flash on and off) when an error occurs.

Step 1

Press the <DOWN> arrow key twice to display the third page of the Configuration Menu.

Step 2

Select `[Sound Menu]` on the Configuration Menu.

Step 3

Select `[Display Blinking]` on the Sound Menu.

The following selections appear on the screen.

- `[Blinking on]`
- `[Blinking off]` (the default)

**NOTE:** The current condition of this function is denoted by an arrow "->" in the selection box.

Step 4

Indicate your choice by selecting the appropriate key.

The display returns to the Sound Menu.

## Selecting a Language

The mini VIDAS system is capable of presenting the menus, messages, and other screen displays in different languages. Use this procedure to select one of the available languages.

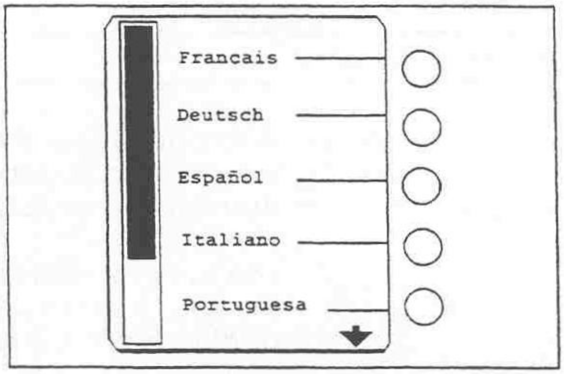
Step 1

Press the <DOWN> arrow key to display the second page of the Configuration Menu.

Step 2

Select `[Select Language]`.

The following screen appears:



Press the <DOWN> or <UP> arrow keys, as needed, until the language you want appears on the screen.

Step 3

Select the language you want to use.

The following message appears:

```
Please wait
```

The screen returns to the Configuration Menu.

Step 4

Press the <ENTER> key to return to the Main Menu.

## Testing the mini VIDAS Instrument

There are a number of simple tests that the mini VIDAS can perform on itself. They provide a quick and easy way to test the display, the keypad, the printer, and the audio output.

It is not necessary to perform any of these tests on a routine basis. They may be needed should it become necessary to troubleshoot a problem in the system.

### Accessing the Tests

All of the hardware tests are found on the Test Menu. Each procedure in this section, therefore, begins with a selection on the Test Menu. Refer to the following diagram for accessing the Test Menu.

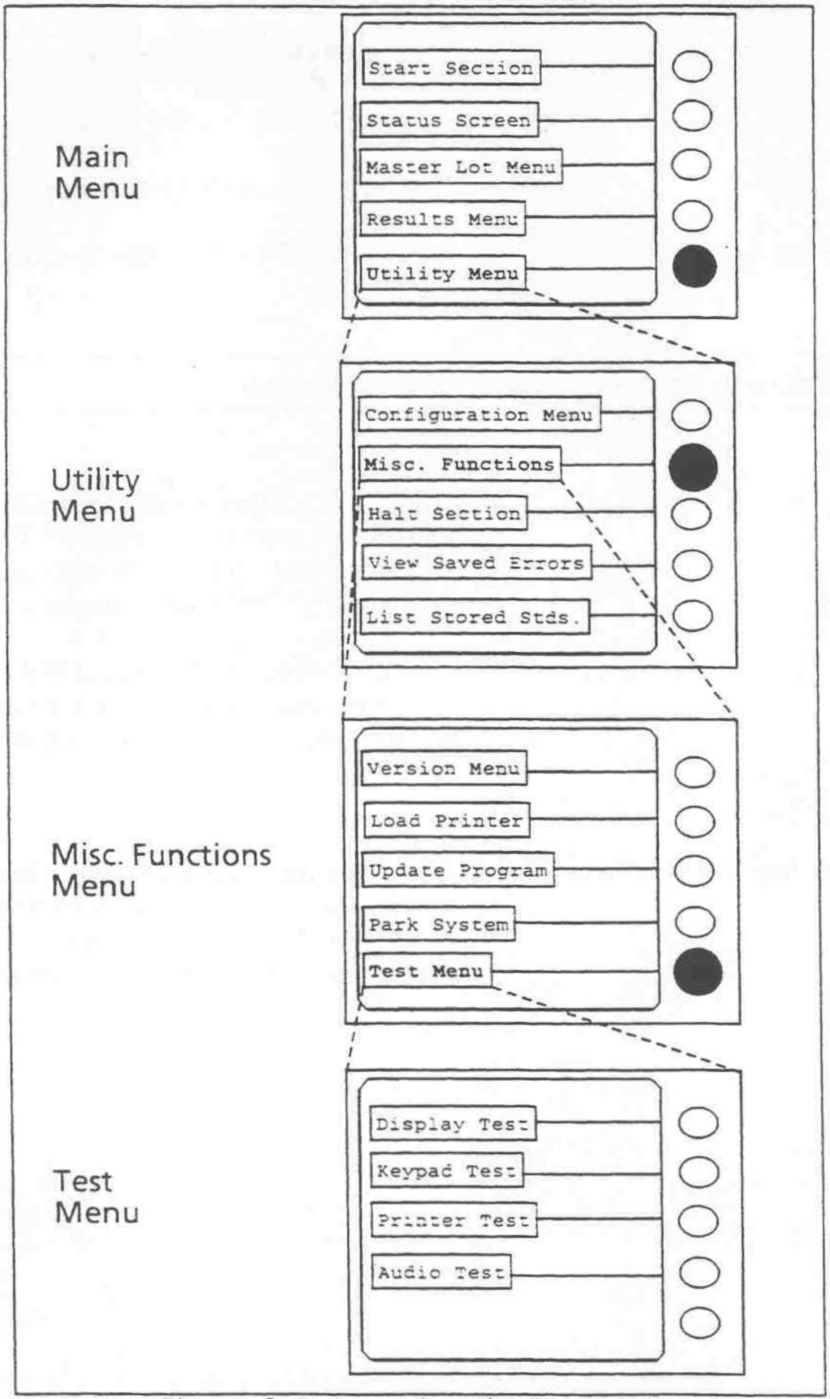

Main
Menu
Start Section
Status Screen
Master Lot Menu
Results Menu
Utility Menu
Utility
Menu
Configuration Menu
Misc. Functions
Halt Section
View Saved Errors
List Stored Stds.
Misc. Functions
Menu
Version Menu
Load Printer
Update Program
Park System
Test Menu
Test
Menu
Display Test
Keypad Test
Printer Test
Audio Test

Figure 6–2 Accessing the Test Menu

## Testing the Display

The mini VIDAS display screen is composed of several hundred individual points called pixels. Letters and other characters are formed by darkening the individual pixels in a pattern that forms the character.

The display test darkens all the pixels on the display. It begins with the first vertical column on the left side of the screen, quickly moving towards the right, column by column.

The failure of any pixel to darken can easily be seen.

Step 1 Select `[Display Test]` on the Test Menu.

The screen clears initially, and then begins to darken, from left to right, as described above.

Step 2 When the entire screen has darkened, inspect it for pixels that have failed to darken. They appear as "holes" in an otherwise dark screen.

Step 3 Press the <Previous Screen> key to return to the Test Menu.

## Testing the Keypad

This test ensures that every key on the keypad is making a proper connection to the system. The test requires that you press every key on the keypad. The system responds with a symbol for each key on the display. The only exception to this pattern is the <?> key, which activates the help screen, as it normally does.

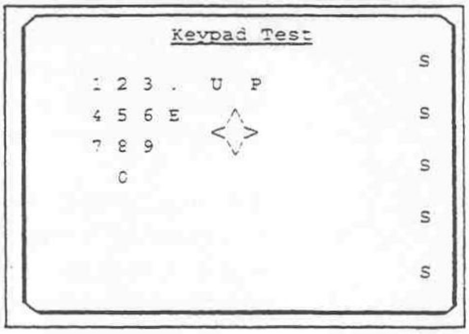
Step 1 Select `[Keypad Test]` on the Test Menu.

The screen clears except for the title

```
Keypad Test
```

Step 2

Begin pressing each key on the keypad. When you are done, the display should be similar to the following:



```
          Keypad Test
                                    S
1 2 3 .   U  P
4 5 6 E     ^                       S
7 8 9     <   >
  0          v                      S

                                    S

                                    S
```

**NOTE:** The last key press ends the test and returns the display to the Test Menu. You therefore do not see that key's symbol on the screen.

After the last key is pressed, the message

```
Keypad okay
```

confirms a passed test.

## Testing the Printer

Testing the printer is a matter of sending a string of known characters and ensuring that those characters are printed.

There are two printer tests, one each for an internal and external printer. The test you use depends on what kind of printer your system is configured to use.

★ See Configuring the mini VIDAS in Chapter 2, for information on selecting a printer.

Step 1

Select `[Printer Test]` on the Test Menu.

The printer should immediately begin to print the following test pattern:

```
ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
```

Failure of the printer to reproduce this test pattern constitutes a failure of this test.

## Testing the Audio Output

This procedure tests the audio output for the system's beep.

Step 1

Select `[Audio Test]` on the Test Menu.

The mini VIDAS should respond with the system's beep tone.

**NOTE:** The display does not change during this test.

## Displaying the System Software Version

Use this procedure to display the version number of the mini VIDAS software.

Step 1

Select `[Utility Menu]` on the Main Menu.

Step 2

Select `[Misc. Functions]` on the Utility Menu.

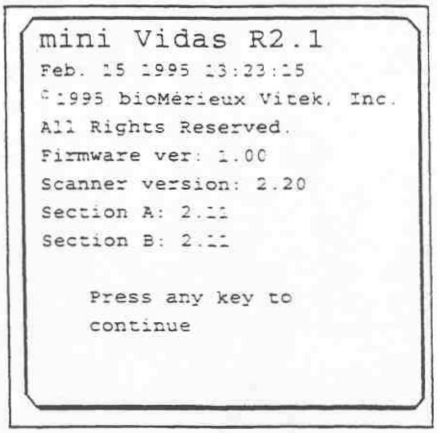
Step 3

Select `[Version Menu]` on the Miscellaneous Functions Menu.

Step 4

Select `[Show Software Version]` on the Version Menu

A screen similar to the following appears:



```
mini Vidas R2.1
Feb. 15 1995 13:23:15
©1995 bioMérieux Vitek, Inc.
All Rights Reserved.
Firmware ver: 1.00
Scanner version: 2.20
Section A: 2.11
Section B: 2.11

    Press any key to
    continue
```

Step 5

Press any key on the keypad to return to the Version Menu.

Step 6

Press the <ENTER> key to return to the Main Menu.

## Printing the System Software Version

Use this procedure to print the version number of the mini VIDAS software.

Step 1 Select `[Utility Menu]` on the Main Menu.

Step 2 Select `[Misc. Functions]` on the Utility Menu.

Step 3 Select `[Version Menu]` on the Miscellaneous Functions Menu.

Step 4 Select `[Print Software Version]` on the Version Menu.

The Software Version begins to print and the display returns to the Version Menu.

Step 5 Press the <ENTER> key to return to the Main Menu.

## Displaying the Assay Version

Use this procedure to display the Assay Version for the selected assay.

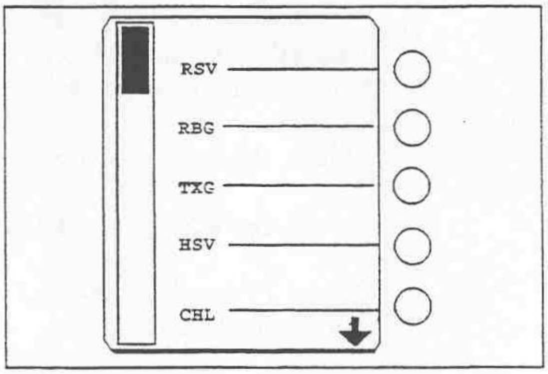
Step 1 Select `[Utility Menu]` on the Main Menu.

Step 2 Select `[Misc. Functions]` on the Utility Menu.

Step 3 Select `[Version Menu]` on the Miscellaneous Functions Menu.

Step 4 Select `[Show Assay Version]` on the Version Menu.

An assay selection list, similar to the following[1], appears:



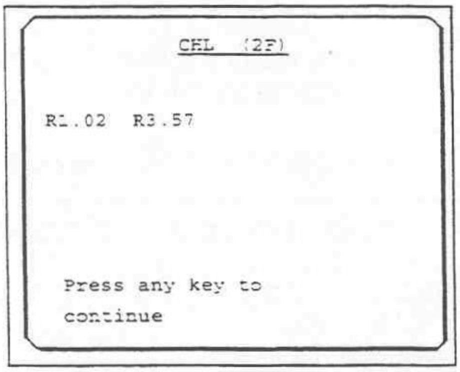
Step 5

Press the <DOWN> or <UP> arrow keys, as needed, until the assay you want appears on the screen.

Step 6

Select an `[assay]`.

A screen similar to the following appears:



CHL (2F)

R1.02 R3.57

Press any key to continue

**NOTE:** There is an intermediate screen for assays that have more than one version.

Step 7

Press any key to return to the assay selection list.

Step 8

Step 8 has two options.

- Press the <ENTER> key to return to the Main Menu.
- Go to Step 5 to display additional assays.

---

[1] The assays that actually appear may be limited by the `[Show All Assays]` configuration option, discussed in Chapter 2.

## Printing the Assay Version

Use this procedure to print the list of assays and their respective versions.

Step 1 Select `[Utility Menu]` on the Main Menu.

Step 2 Select `[Misc. Functions]` on the Utility Menu.

Step 3 Select `[Version Menu]` on the Miscellaneous Functions Menu.

Step 4 Select `[Print Assay Version]` on the Version Menu.

The following message appears:

```
Constructing assay list
printout.

Please wait...
```

The assay list then begins to print and the display returns to the Version Menu.

A portion of an assay list printout appears below.

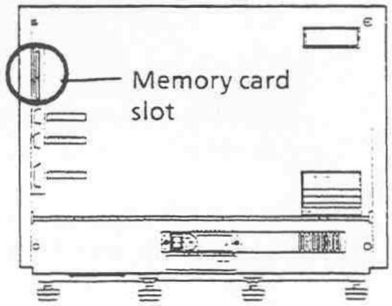
```
07:42:43 16Nov93 ADD LONG NAMES

THEO    (1M):
  TU    (1O):
CKMB    (B7):
  E2    (AS):
 FHS    (AR):
  LH    (AQ):
 PRL    (AU):
 PSA    (AY):
 AFP    (AX):
 FER    (AV):
 FER    (C6):
 HCG    (C7):
 HCG    (AP):
 IGE    (B2):
```

Step 5 Press the <ENTER> key to return to the Main Menu.

## Updating the mini VIDAS Software via the Memory Card

Use this procedure to install revised system software or protocols in the mini VIDAS. These updates are sent to you by bioMérieux Vitek on memory cards. An accompanying letter details the update.

Step 1 Place the memory card in the slot on the back of the instrument. See the figure below for the location of the memory card slot.



The memory card is placed in the slot with the end containing the two rows of connector holes inserted first. Apply gentle pressure on the center of the card to seat it. The ejection button, located below the slot, pops up when the card is properly seated. The card itself is keyed so that it cannot be seated improperly.

Step 2 Select `[Utility Menu]` on the Main Menu.

Step 3 Select `[Misc. Functions]` on the Utility Menu.

Step 4 Select `[Update]` on the Miscellaneous Functions Menu.

The following prompt appears:

```
Software update.  Are you
certain?
```

The prompt is accompanied by `[Yes]` and `[No]` selections.

Step 5

Select `[Yes]` to begin the update.

**NOTE:** Make sure that you have inserted the memory card into its slot. See Step 1.

**NOTE:** Once an update begins, it cannot be interrupted.

The following messages appear:

```
Updating

Please wait...
```

In approximately two minutes, a bar graph appears with the messages. As the update proceeds, the bar graph fills to indicate the progress of the update.

About 30 seconds after the bar graph fills completely, the following messages appear:

```
Update complete. Cycle power now.
```

Step 6

Push the ejection button below the memory card slot to unseat the card. Remove the card from the slot.

Step 7

Reach behind the mini VIDAS and turn the power off.

Step 8

Turn the power back on after about 15 seconds.

The mini VIDAS goes through its power up sequence, ending with the appearance of the Main Menu.

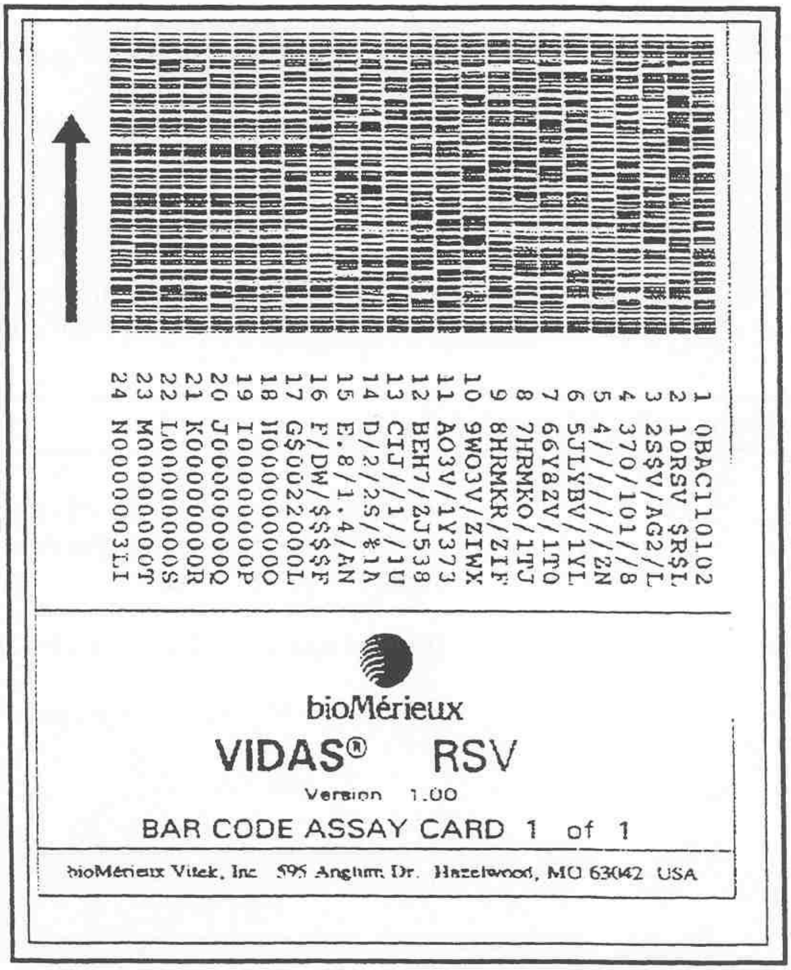
The mini VIDAS update is now complete.

**NOTE:** You can use the preceding procedure, Displaying the Software Version, to display the new version number.

## Updating the mini VIDAS Software via the BAP Card

Use this procedure to install revised system software or protocols in the mini VIDAS. These updates are sent to you by bioMérieux Vitek on Barcode Assay and Protocol (BAP) Cards. An accompanying letter details the update. The BAP Card is placed into a specially designed holder and then inserted into a Section of the mini VIDAS Module.

Following is a sample BAP card.Step1



```
1  0BAC110102
2  10RSV $R$L
3  2S$V/AG2/L
4  370/101//8
5  4///////2N
6  5JLYBV/1YL
7  66Y82V/1TO
8  7HRMKO/1TJ
9  8HRMKR/ZIF
10 9WO3V/ZIWX
11 AO3V/1Y373
12 BEH7/2J538
13 CIJ//1//1U
14 D/2/2S/%1A
15 E.8/1.4/AN
16 F/DW/$$$$F
17 G$0022000L
18 H00000000O
19 I00000000P
20 J00000000Q
21 K00000000R
22 L00000000S
23 M00000000T
24 N0000003LI
```

bioMérieux

VIDAS® RSV

Version 1.00

BAR CODE ASSAY CARD 1 of 1

bioMérieux Vitek, Inc. 595 Anglum Dr. Hazelwood, MO 63042 USA

Select `[Load BAP Card]` on the Utility Menu.

Step 2 Place the BAP Card in the specially designed holder and slide it into the Section you selected.

Step 3 Select either `[Section A]` or `[Section B]`.

**NOTE:** Both Sections must be idle before loading the BAP Card.

The mini VIDAS reads the bar coded data from the BAP card. If this card is part of a multi-card set, the mini VIDAS prompts you to insert the next BAP card.

After the BAP card data is read into the mini VIDAS, a prompt appears asking you if you want to load another BAP card.

Step 4

Step 4 has two options:

- Answer *yes* to load another BAP card.

  Go back to Step 2.

- Answer *no* to end BAP data input.

  A message tells you to remove the BAP card and to reboot the system.

Step 5

Power off the mini VIDAS and then reboot.

★ Refer to the procedure in chapter 2 of this manual, Starting the mini VIDAS.

## Verifying the Memory Card Data

Use this procedure to verify the data on the memory card that is installed in the memory card slot on the back of the mini VIDAS.

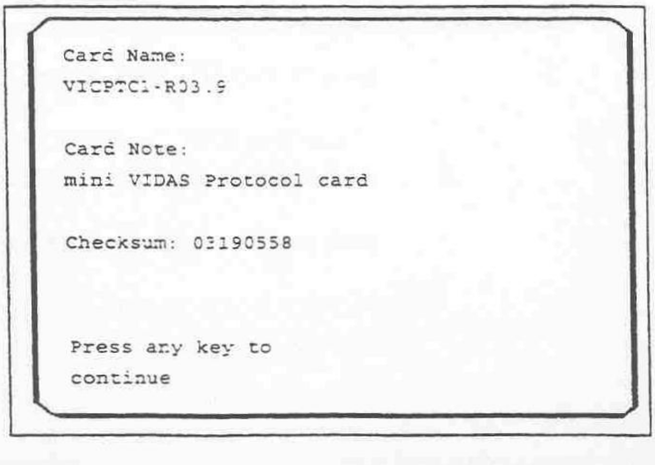
Step 1

Select `[Card Info.]` on the Utility Menu.

The following message appears:

```
Scanning....
```

After the system reads the card, a screen similar to the following appears:



```
Card Name:
VICPTC1-R03.9

Card Note:
mini VIDAS Protocol card

Checksum: 03190558


 Press any key to
 continue
```

Step 2 Press any key to return to the Utility Menu.

## Backing Up Configuration and Master Lot Data

Use this procedure to store the system configuration options and Master Lot Data on a memory card.

Step 1 Place a write-enabled memory card in the slot on the back of the instrument.

Step 2 Select `[Utility Menu]` on the Main Menu.

Step 3 Press the <DOWN> arrow to display the second page of the Utility Menu.

Step 4 Select `[Backup Data]` on the Utility Menu.

The following message appears:

```
Data on the card will be changed.
Are you certain?
```

This message refers to the fact that there should be nothing on this memory card that you need to keep.

Step 5 Select `[Yes]` to continue with the backup.

The following messages appear:

```
Copying. Please wait

Backup completed successfully
Press any key to continue
```

Step 6 Press any key to return to the Utility Menu.

**NOTE:** If the copy operation fails, make sure that the memory card is properly seated in the slot. The eject button should pop up when the card is properly seated.

## Restoring Configuration and Master Lot Data

Use this procedure to restore the system configuration options and Master Lot Data from a memory card.

Step 1 Place a memory card in the slot on the back of the instrument.

Step 2 Select `[Utility Menu]` on the Main Menu.

Step 3 Press the <DOWN> arrow to display the second page of the Utility Menu.

Step 4 Select `[Restore Data]` on the Utility Menu.

The system checks the memory card to see if it is properly seated and contains the right information. If the memory card is acceptable, the following message appears:

```
Internal data will be changed.
Are you certain?
```

This message means that the data restored from the memory card overwrites the data in the mini VIDAS.

Step 5 Select `[Yes]` to continue.

In a few moments, the following message appears:

```
Restore completed successfully.

Press any key to continue.
```

Step 6 Press any key to return to the Utility Menu.

## Shipping the mini VIDAS

Use this procedure to prepare the mini VIDAS for shipment in its original shipping container.

**What You Will Need** The following are required for this procedure:

- The original mini VIDAS shipping container
- The two foam end caps and bottom support for the instrument
- The antistatic bag for the instrument
- The two shipping blocks, one with an 11-inch long wooden dowel

**CAUTION**

Follow this procedure carefully to prevent the possibility of damaging sensitive electronic and optical parts in the instrument.

Step 1

Select `[Utility Menu]` on the Main Menu.

Step 2

Select `[Misc. Functions]` on the Utility Menu.

Step 3

Select `[Park System]` on the Miscellaneous Functions Menu.

The following prompt appears:

```
Parking disables the instrument.
Are you certain?
```

The prompt is accompanied by `[Yes]` and `[No]` selections.

Step 4

Select `[Yes]` to park the system.

**NOTE:** From this point, the parking process cannot be interrupted.

The following things occur:

- You hear the scan head moving inside the instrument. It is being placed in its parking position.
- You hear other motors working as other parts of the system are placed in their parking positions.
- The two Reagent Strip trays are retracted fully into the instrument.

When the system is fully parked, the status lights on each Section blink.

Step 5

Reach behind the instrument and turn the power off. You can also remove the AC power cord at this time.

Step 6

Open the dust cover of Section A. Take the shipping block with the long wooden dowel and place it in Section A.

The orientation of the shipping block is such that the portion of the block with the dowel is on **TOP.** The block is inserted, **DOWEL FIRST,** so that the dowel goes into Reagent Strip Position 3.

Push the shipping block completely into the Section so that it occupies the space previously taken by the Reagent Strip tray.

Step 7

Open the dust cover of Section B. Place the other shipping block (the one without the dowel) completely into the Section so that it occupies the space previously taken by the Reagent Strip tray. Use the same orientation as you did for the block in Section A.

Step 8

Close the reagent tray dust covers and secure them with a piece of adhesive tape over the space between the two covers.

Step 9

Remove the paper roll from the printer. Replace the spindle in its slots and secure it with adhesive tape. Close the printer door.

Step 10

Carefully lift one end of the mini VIDAS and place the antistatic bag over the elevated end of the instrument.

**NOTE:** The mini VIDAS instrument weighs 84 lb (38.18 kg). It is recommended that two people perform this step.

Step 11

Repeat Step 10 at the other end of the instrument.

Step 12

Place the foam end caps on each end of the instrument.

**NOTE:** The end caps are not interchangeable.

Step 13

Insert the bottom support (a piece of cardboard with two foam blocks attached) into the bottom of the shipping box. The foam blocks should be face up.

Step 14

Lift the mini VIDAS and place it in the shipping container so the channel formed by the two metal strips in the center of the instrument fits between the two foam end caps.

**CAUTION**

The mini VIDAS instrument weighs 84 lb (38.18 kg). Two people should lift the mini VIDAS from the benchtop and place it in its carton.

Step 15

Close the box and secure it with appropriate adhesive tape.

# 7. Error Handling

## Introduction

The mini VIDAS system has several ways to inform you that there is a problem in the system. This chapter shows you how the system alerts you to a problem, the various error messages you may see, and, in some cases, what you can do to correct the error condition.

The following types of errors are covered:

- Start Errors 7-3
- System Errors 7-8
- Assay Report Errors 7-13
- Printer Errors 7-14

This chapter also covers the following topics:

- Error Message Alert System 7-2
- Viewing Saved Errors 7-15
- Displaying Instrument Temperatures 7-16
- Printing Instrument Temperatures 7-16

## The Error Message Alert System

The mini VIDAS has a system for alerting you to the presence of an error. There is an audio cue (a beep) and an optional video cue (the display blinks). Both the audio and visual cues are controlled by configuration options:

- Error beep. You can set the volume of the beep the system emits when there is an error. There are configuration options to set an initial volume and a final volume. The initial volume is the volume used when the beep begins. The volume then increases until you respond, or until it reaches the final volume. Both volumes can be set to the same level so that there is no increase in loudness.
- Display blink. There is a configuration option in which you can enable or disable a display blink to accompany the error beep.

★ See Chapter 6 for procedures to set these configuration options.

### Responding to an Error Alert

When the system alerts you to the presence of an error condition, press the <?> key to respond. This action terminates the error beep and, if enabled, the display stops blinking.

Whatever was being displayed when you pressed the <?> key is replaced by an error message screen. The format of the message screen depends on the type of error.

### Types of Error Message Screens

There are two basic types of error message screens. One type is used when there is a start error. A start error occurs during the initial processing of a run of Reagent Strips.

The other type of error message screen is used for all other types of messages. It consists of an error code number and the error message itself.

In the sections that follow, all the types of errors and error screens are described in detail.

## Start Errors

A start error can occur when you start a Section. The mini VIDAS goes through a series of preprocessing steps that include reading the bar code on the label of each Reagent Strip, and performing an optical check of the substrate.

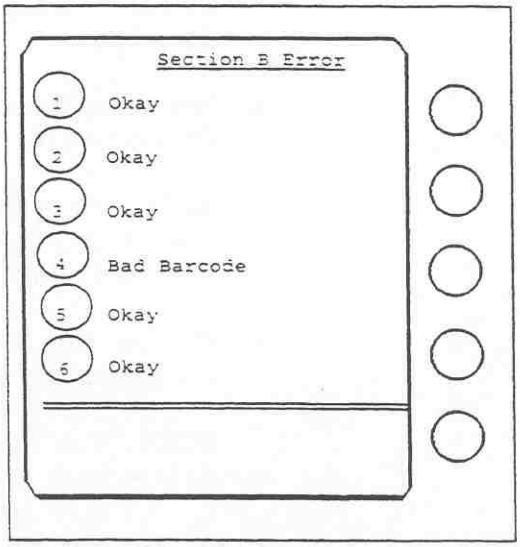
**What Happens?**

When a start error occurs, the system responds in the following ways:

- Error alert. The normal error alert begins. The system beeps and, if enabled, the display blinks.
- Halt. A start error causes the system to halt the run in the Section containing the error. The other Section is not affected by any of this action.

**What You Should Do**

Press the <?> key to display the error message screen. (This action also stops the error beep.) The figure below is an example of a possible error message screen for a start error. The screen displays the status of each Position within the Section having the error.



Section B Error
1 Okay
2 Okay
3 Okay
4 Bad Barcode
5 Okay
6 Okay

Notice that, for all of the Positions except B4, the status is shown by "Okay." These Positions have no errors.

Position B4, however, shows a status of "Bad barcode." This message indicates the start error.

The possible start error messages are

- Bad Barcode. The system was unable to read the bar code on the Reagent Strip.
- Bad Sub. The initial fluorescence reading of the substrate is not acceptable.
- Incompatible. The assay in this Position is not compatible with other assays in the Section.

  **NOTE:** This type of error should occur only in a Load and Go run. In a defined run, the system prevents the entry of incompatible assays.
- Misaligned. A Dual Reagent Strip has been placed in the wrong Positions.

  **NOTE:** This type of error should occur only in a Load and Go run. In a defined run, the system would detect a misaligned Dual Reagent Strip.
- Okay. There is no error in this Position.
- No Strip. An assay was specified for this Position but no Reagent Strip was found.

  **NOTE:** This type of error should occur only in a defined run.
- Unknown Assay. There is no protocol stored in the system for the assay type.

  **NOTE:** This type of error should occur only in a Load and Go run. In a defined run, the system does not allow the entry of an unknown assay.
- Wrong Type. The type of assay specified for this Position is different than the one found.

  **NOTE:** This type of error should occur only in a defined run.

### How to Resolve Start Errors

In the preceding subsection, you saw that by pressing the <?> key, you access the error message screen. This screen tells you the type of start error in the Section. There are two general categories of responses, depending the type of error:

- For all start errors **EXCEPT** a bad bar code error, you attempt to resolve the condition by manipulating the Reagent Strip in some way. Details are given in the following subsection, Remedies for Start Errors.

- For a bad bar code error, you must enter the bar code manually. The procedure for manual bar code entry follows the remedies for the other start errors.

## Remedies for Start Errors (Except Bad Bar Code)

Step 1

Perform the following, depending on the type of error.

- Bad substrate
  - Make sure the optical cuvette on the Reagent Strip is clean.
    --OR--
  - Replace the Reagent Strip.

- Incompatible
  Run the Reagent Strip in the other Section or in a different run.

- Misaligned
  Applies to Dual Reagent Strips. Move the strip so that it occupies an acceptable pair of Positions: 1&2, 3&4, or 5&6.

- No strip
  Place a Reagent Strip in the appropriate Position or delete the entry for that Position.

- Unknown assay
  Remove the Reagent Strip.

- Wrong type
  Put the Reagent Strips in their proper Positions or correct the test entries.

Step 2

Press <Previous Screen> from the error message screen.

The following selections are displayed:

- `[Restart]`

- `[Cancel]`

Step 3

Step 3 has two options:

- Select `[Cancel]` to abort the run.

  The system returns to the state it was in before the run was started.

  Any data you entered about the assays is retained.

- Select `[Restart]` to restart the run.

  The run resets and begins with another bar code read and substrate check.

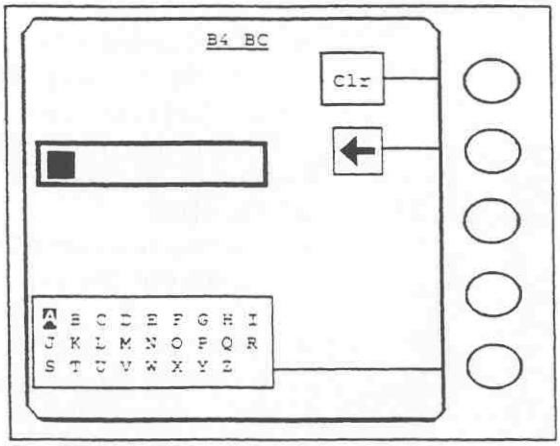
## Manually Entering Bar Codes

This procedure begins from the error message screen display.

Step 1

Press the <Number Key> corresponding to the Position containing the bar code error.

The manual bar code entry screen appears:



Step 2

Remove the Reagent Strip from the Section and find the eight-digit alphanumeric bar code, located next to the assay code.

Step 3

Manually enter the bar code as follows:

- For a digit, press the appropriate <Number Key>

- For a letter, press the <UP>, <DOWN>, <LEFT>, and <RIGHT> arrow keys to highlight the appropriate character in the character box, then select the [character box]

Alternately, use these functions:

- `[Clr]` to clear the cursor box
- `[←]` to delete one character in front of the cursor

Step 4

Press <Previous Screen> when the bar code entry has been completed.

The system checks the bar code you entered.

- If the bar code is valid, the display returns to the Error message screen.

  Go to Step 6.

- If the bar code is not valid, the following message is displayed:

  ```
  Warning bar code still invalid
  Press any key to continue
  ```

  Go to Step 5.

Step 5

Press any key on the keypad.

The display returns to the error message screen.

To reenter the bar code, go to Step 1.

Step 6

Press <Previous Screen>.

The following selections appear:

- `[Restart]`
- `[Cancel]`

Step 7

Step 7 has two options:

- Select `[Cancel]` to abort the run.

  The system returns to the state it was in before the run was started.

  Any data you entered about the assays is retained.

- Select `[Restart]` to restart the run.

  The run resets and begins with another bar code read and substrate check.

## System Errors

System errors comprise a broad range of error conditions. In all cases, when the system detects one of these errors, the error beep starts to sound, and, if enabled, the display begins to blink.

These error alert cues continue until you respond to the error condition by pressing the <?> key. This action causes the system to display an error message screen. The text on the screen is similar to the following:

```
Errorcode: 73
Time: 14:53 09/14/92
Master Lot Data Bad
```

An error message display consists of three lines:

- Line 1. This line contains a number that corresponds to the specific error. Make note of this number in case you need to contact bioMérieux Vitek.

  This line also contains the word "Saved." The system maintains a log of the last ten error messages produced by the system. They are saved unless system power is shut off. You can access stored error messages via the View Saved Errors function.

  ★ See the section on viewing saved errors later in this chapter.

- Line 2. This line contains the time and date that the error message was produced.
- Line 3. This line contains the actual error message text. These messages are detailed in alphabetical order, starting on the next page.

## Error Messages

Listed below, in alphabetical order, are all of the error messages programmed into the system. In some cases, there are suggestions for corrective action. Where no corrective action is possible, or if the corrective actions fail, the final action is to call bioMérieux Vitek customer support.

- **Assay data load failed.** The system cannot read the protocol memory card. Make sure the protocol memory card is in the memory card slot. Reinsert the memory card to ensure proper contact. Retry the last operation. If the error recurs, call bioMérieux Vitek.
- **Assay failed.** The assays in a Section have failed to process correctly. Retry an assay in the same Section. If the error recurs, call bioMérieux Vitek.
- **Assay processing error.** The assays in a Section have failed to process correctly. Retry an assay in the same Section. If the error recurs, call bioMérieux Vitek.
- **Assay start failed.** This error would appear during the preprocessing steps of a run. Perform the procedure to halt the Section. Retry an assay in the same Section. If the error recurs, call bioMérieux Vitek.
- **BAP card data save failed.** This error would appear after a BAP card read. Perform the BAP card read procedure again. If the error recurs, call bioMérieux Vitek.
- **Boot EPROM obsolete.** This error would appear during the power-on startup sequence. Turn the system power off and then on again to restart the system. If the error recurs, call bioMérieux Vitek.
- **Cannot begin assay - check door.** Check to see that the door to the SPR compartment is completely closed and restart the assay. If the error recurs, call bioMérieux Vitek.
- **Cannot begin bar code read - check door.** Check to see that the door to the SPR compartment is completely closed and restart the assay. If the error recurs, call bioMérieux Vitek.
- **Communications error.** Retry the operation that created the error. If the error recurs, call bioMérieux Vitek.

- **Configuration data not found.** This error would occur during the power-on startup sequence. Note that any previously entered configuration options are lost, and the options have returned to their default states. Enter one or two configuration changes. Repeat the power up start sequence. If the error recurs, call bioMérieux Vitek.
- **External printer error.** The external printer has sent an error signal to the mini VIDAS. Consult your printer manual.
- **External printer offline.** The external printer has sent an offline signal to the mini VIDAS. Press the online button on the printer, or consult your printer manual.
- **External printer paper empty.** The external printer has sent a signal to the mini VIDAS indicating it is out of paper. Reload the printer with paper. If the printer still has paper, check the cable connections between the printer and the mini VIDAS. Consult your printer manual if necessary.
- **Hardware failure.** Turn power to the system off. Perform the power-on startup sequence. Retry another assay. If the error recurs, call bioMérieux Vitek.
- **Instrument has been too busy for autocalibration to occur.** Allow the system to sit idle (not performing assays) for at least two hours. Continue normal operations. If the error recurs, call bioMérieux Vitek.
- **Internal printer error.** Retry a print operation. If the error recurs, call bioMérieux Vitek.
- **Internal printer paper empty.** Install another roll of paper in the thermal printer. Attempt another print operation. If the error recurs, call bioMérieux Vitek.
- **Master Lot Data bad.** The instrument failed to read a Master Lot Data card. Inspect the card for proper placement in the Reagent Strip tray, debris, or smudges. Replace or reinsert, as necessary. Retry the read operation, or enter the data manually. If the error recurs, call bioMérieux Vitek.

- **Master lot read failed.** This error is probably due to a bad bar code on the MLE card. Perform the automatic read procedure again. If the error recurs, enter the data manually.
- **Master Lot Save failed.** Attempt to reenter the Master Lot Data. If the error recurs, call bioMérieux Vitek.
- **New LIS results have been discarded due to full queues.** This message appears after other messages warning you that the LIS result validation or upload queues are full. To resolve this situation, you must use the result validation and upload procedures to reduce the number of results in those queues.
- **No assay data.** The system cannot read the protocol memory card. Make sure the protocol memory card is in the memory card slot. Reinsert the memory card to ensure proper contact. Retry the last operation. If the error recurs, call bioMérieux Vitek.
- **Normal range load failed.** Call bioMérieux Vitek.
- **Normal range save failed.** Call bioMérieux Vitek.
- **Optical hardware failure.** Turn power to the instrument off. Perform the power-on startup sequence. If the error recurs, call bioMérieux Vitek.
- **Optics autocalibration data corrupt -- instrument may be out of calibration.** Call bioMérieux Vitek.
- **Pump mechanism failure.** Check the area inside the SPR compartment for any physical obstructions that could cause a jam. Run a TP4 assay. If the error recurs, call bioMérieux Vitek.
- **Scan head motor failure.** Turn the instrument power off. Remove the lower front cover and look inside for any physical obstructions that could cause a jam. Retry the operation. If the error recurs, call bioMérieux Vitek.
- **Scan head motor movement becoming restricted.** Turn the instrument power off. Remove the lower front cover and look inside for any physical obstructions that could cause a jam. Call bioMérieux Vitek to report this message.

- **Scanner Board failure.** Turn power to the instrument off. Perform the power-on startup sequence. If the error recurs, call bioMérieux Vitek.
- **Scanner board memory almost full.** Call bioMérieux Vitek to report this message.
- **Section communications error.** Halt the Section with the error. Retry an assay in the same Section. If the error recurs, place the Section offline and call bioMérieux Vitek.
- **Section hardware failure.** Turn power to the instrument off. Perform the power-on startup sequence. If the error recurs, halt the Section, place it offline, and then call bioMérieux Vitek.
- **Section reset failed.** Check the Section for physical obstructions or any jams. Perform the halt operation on the Section. If the error recurs, call bioMérieux Vitek.
- **Software failure.** Call bioMérieux Vitek.
- **Some Section errors lost due to overflow.** This message may occur after repeated Section errors. Call bioMérieux Vitek to report this message.
- **Some scanner errors lost due to overflow.** This message may occur after repeated scanner errors. Call bioMérieux Vitek to report this message.
- **SPR temperature out of allowed range.** Check the temperature of the SPR block. If the temperature is low, make sure all doors on the mini VIDAS are closed. Allow time for the temperature to equilibrate. If the error continues, call bioMérieux Vitek.
- **Standard save failed.** Call bioMérieux Vitek.
- **Temperature monitoring failed.** Allow any assays that are running to complete. Turn the power to the instrument off. Perform the power-on startup sequence. If the error recurs, call bioMérieux Vitek.

- **Tower mechanism failure.** Check the area inside the SPR compartment for any physical obstructions that could cause a jam. Run a TP5 assay. If the error recurs, call bioMérieux Vitek.

- **Tray mechanism failure.** Check the Reagent Strip tray area for any physical obstructions that could cause a jam. Also check the tray to see that it is on its track. This is especially important after decontaminating the instrument. Run a TP6 assay. If the error recurs, call bioMérieux Vitek.

- **Tray temperature out of allowed range.** Check the temperature of the Reagent Strip tray. If the temperature is low, make sure all doors on the mini VIDAS are closed. Allow time for the temperature to equilibrate. If the error continues, call bioMérieux Vitek.

- **Unable to complete LIS upload of results.** The mini VIDAS was unable to transfer its results. First check all cable connections between the mini VIDAS and the LIS computer. Also, make sure that your LIS computer is ready to receive data.

- **Unable to initialize Section.** This error would occur during the power-on startup sequence. Turn power to the instrument off. Check the instrument for physical obstructions or other possible jams. Perform the power-on startup sequence again. If the error recurs, call bioMérieux Vitek.

- **Unknown scanner error.** Call bioMérieux Vitek.

- **Unknown section error.** Call bioMérieux Vitek.

- **Unknown software error.** Call bioMérieux Vitek.

- **Warning LIS validation queue full.** The validation queue is a temporary storage area for results waiting to be validated. Use the results validation procedure to remove results from this queue. **NOTE:** assay results will be lost if you fail to respond to this warning.

- **Warning LIS upload queue full.** This message indicates a possible problem in the mini VIDAS to LIS interface. See the message "Unable to complete LIS upload of results."

## Assay Report Errors

Errors related directly to results on an assay report are not displayed on an error screen. Rather, the assay report itself is used to report these errors.

The assay report uses a set of symbols to mark the part of the report that contains the error. A footnote then appears at the bottom of the report, referencing the same symbol. The footnote includes the error message.

### Correcting Assay Report Errors

In all cases, the test should be repeated. If the error recurs and you suspect a problem in the system, call bioMérieux Vitek.

### Assay Report Error Symbols

Following are the symbols used on assay reports and their corresponding error messages:

- & Low reading. A fluorescence reading for the Reagent Strip is below a preset limit.
- § High reading. A fluorescence reading for the Reagent Strip is above a preset limit.
- ¥ Off-scale reading. A fluorescence reading for the Reagent Strip is outside the operating range of the detector.
- # Low RFV. An RFV for the Reagent Strip is below a preset limit.
- ! High RFV. An RFV for the Reagent Strip is above a preset limit.
- { No reading. Call bioMérieux Vitek.
- ¬ Math error. The system encountered a calculation error, e.g., a divide by zero.
- @ High test value. A test value calculated for the Reagent Strip is above a preset limit.
- ¤ Low test value. A test value calculated for the Reagent Strip is below a preset limit.
- ¢ Discrepant control. A positive control is giving an equivocal or negative response (or vice versa).
- ˜ Low control. A high control is giving a low response.

- ¶ High control. A low control is giving a high response.
- ¿ Off curve. The result for a quantitative assay is beyond the limits of the assay's calibration curve.
- \$ Std. CV exceeded. The coefficient of variation (CV) for the standard result is greater than a preset limit.
- £ Invalid std. The result for the standard is invalid and cannot be used to calculate the result for the test samples.

## Printer Errors

If the internal printer is out of paper or does not respond, the mini VIDAS will keep retrying for 30 seconds and then sound the error beep.

Use this procedure to resolve printer errors.

Step 1

Press the <?> key to display the error message screen.

The error message refers to the internal printer.

Step 2

Replace the printer paper if error indicates the printer is out of paper.

Step 3

Press <Previous Screen>.

The following selections are displayed:

- `[Retry Printing]`
- `[Abort Printing]`

Step 4

Step 4 has two options:

- Select `[Abort Printing]` to tell the printer to stop trying to print at this time.

  The system will try to print this job again if

  - The printer is told to print something else.
  - You use the Select Printer function on the Configuration Menu.

- Select `[Retry Printing]` to try to print the job at this time.

## Viewing Saved Errors

The mini VIDAS stores the last ten error messages it creates. These messages remain in the system unless the power is turned off.

Use the following procedure to access the stored error messages.

Step 1 Select `[Utility Menu]` on the Main Menu.

Step 2 Select `[View Saved Errors]` on the Utility Menu.

The screen displays an error message similar to the following:

```
Errorcode: 73   (Saved)
Time: 14:53 09/14/92
Master Lot Data Bad
```

**NOTE:** The first message shown is the newest message stored in the message file.

Step 3 Step 3 has two options:

- Press the <ENTER> key to display the next message.
- Press the <Previous Screen> key to return to the Utility Menu.

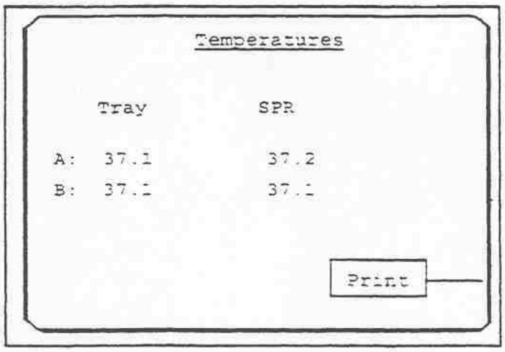
## Displaying Instrument Temperatures

Use this procedure to display the temperature readings for the SPR block and the Reagent Strip tray.

Step 1 Select `[Status Screen]` on the Main Menu.

Step 2 Select `[Display temperatures]`.

A screen similar to the following appears:



```
              Temperatures

     Tray            SPR

A:   37.1            37.2
B:   37.1            37.1

                              Print
```

Step 3 Press the <Previous Screen> key to return to the Main Menu.

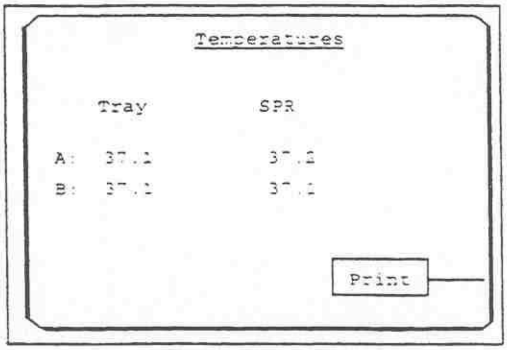
## Printing Instrument Temperatures

Use this procedure to print a copy of the temperature readings for the SPR block and the Reagent Strip tray.

Step 1 Select `[Status Screen]` on the Main Menu.

Step 2 Select `[Display temperatures]`.

A screen similar to the following appears:



```
              Temperatures

     Tray            SPR

A:   37.1            37.1
B:   37.1            37.1

                              Print
```

Step 3 Select `[Print]`.

The temperature begins to print and the screen returns to the Main Menu.

# Appendix A Specifications

## Environmental Requirements

- Ambient room temperature for the instrument should be kept within the limits of +15° to +30°C (59° to 86°F).
- Relative humidity should be kept within the limits of 10 to 80%, non-condensing.

## Physical Space Requirements

- mini VIDAS dimensions:
  21 ¼ inches (54 cm) wide; 21 inches (53 cm) deep; 17 ¼ inches (44 cm) high.
- Add the following minimum air gaps to ensure adequate ventilation:

  Each side: 2 inches (5.08 cm)
  Top: 2 inches (5.08 cm)
  Back: 4 inches (10.16 cm)

## Electrical Requirements

- Voltage: 100/130 VAC, 1.5 amps
  200/250 VAC, 0.8 amps
- Fuse current: 1.5A (Slo-Blow), at 120V
  1.6A (Slo-Blow), at 220V
- Frequency: 50/60 Hz
- Power: 180 watts (maximum); 75 watts (nominal)
- Heat: 256 Btu/hr (nominal)

**Warning:** Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

**NOTE:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

## Temperature Control

Absolute Accuracy: SPR: 36° - 38°C
Tray: 35° - 38°C

## Pumping Precision

% CV at volume: 3.5% at 10 µl
1.5% at 100 µl
1.5% at 200 µl

## Optics

Range: 1 to 16000 RFUs
40 nM - 40,000 nM 4MU

Accuracy: 0.4 RFU/nM ± 10%

# Appendix B Maintenance Procedures

**Decontamination**

Decontamination involves

- Routine decontamination, which should be performed on a periodic basis
- Cleanup of accidental spills, which should be handled immediately

**WARNING**

Before you perform any decontamination procedures, please adhere closely to these precautions to minimize health risks:

- Prior to any decontamination procedures, the mini VIDAS Power Switch must be moved to the OFF position. Power to the mini VIDAS must be disconnected.
- Disposable powder-free, latex, vinyl, or polyethylene gloves should be worn whenever skin contact with potentially infectious material is possible. Also wear gloves when using disinfectants.

**CAUTION**

Be careful not to allow any disinfectant solution to spill into the electrical components of the mini VIDAS.

**CAUTION**

Do not use a spray cleaner of any type on the mini VIDAS.

## Routine Decontamination

The following decontamination procedures should be performed in the time intervals indicated[1] and prior to any type of service or maintenance:

SPR Block (Daily*)

1. Read and follow the precautions given on the previous page.
2. Carefully remove the used Reagent Strips and SPRs and dispose of them according to acceptable procedures for biohazardous material.
3. Open the SPR compartment door and tilt the SPR block towards you. Moisten a dacron swab in a detergent solution (i.e. Liqui-Nox or equivalent) and carefully cleanse inside each SPR sleeve.
4. Moisten a foam or gauze sponge with the detergent solution. Holding the sponge with a curved forceps, swab the underside and back of the SPR block.
5. Repeat Steps 3 and 4 with a **10% bleach solution**.
6. Allow the bleach solution to react for 10 minutes.
7. Rinse each area thoroughly with a sponge or swab moistened with distilled water.
8. Close the SPR compartment doors.
9. Turn the mini VIDAS AC power switch ON.

---

[1] Time intervals may be longer as determined by the individual laboratory if few or no tests are run.

## Reagent Strip Compartment, External Surfaces (Weekly)2

1. Read and follow the precautions given on the previous page.
2. Pull off the panel on the front of the mini VIDAS Module below the Reagent Strip trays. Manually pull the Reagent Strip trays to their outermost position.
3. Moisten a foam or gauze sponge in a detergent solution. Holding the sponge or square with curved forceps, clean the metal Reagent Strip tray by sliding it along each channel. Make sure the sponge or square makes contact with the entire length of the Reagent Strip channel.
4. Remove the plastic tray that sits underneath each Reagent Strip tray by sliding it towards you. Cleanse each tray with a gauze sponge moistened with the detergent solution.
5. Carefully clean the Reagent Strip compartment, compartment cover, and its surrounding external surface area with the detergent solution.
6. Clean the front of the mini VIDAS Module with a detergent solution.
7. Repeat Steps 3 through 6 with **a 10% bleach solution.**
8. Allow the bleach solution to react for 10 minutes.
9. Rinse each area thoroughly with a sponge or swab moistened with distilled water.
10. Push the Reagent Strip trays back in until they engage the tray drive mechanism. You will feel a slight resistance during engagement.

---

2 Time intervals may be longer as determined by the individual laboratory if few or no tests are run.

11. Carefully replace each Reagent Strip tray. The edges of the tray must fit into the grooves on each side. The tray wire must slide on the top of the tray. Replace the front panel.
12. Turn the mini VIDAS AC power switch to ON. The instrument will reset and the Reagent Strip trays will move into the correct position.

Accidental Spills

In the event of accidental spill due to instrument or operator error:

1. **Immediately** turn the mini VIDAS power switch to the OFF position. Contain the spill with a gauze sponge. Absorb the spill with gauze and discard it according to acceptable procedures for biohazardous material.
2. Moisten a gauze sponge with detergent (i.e., Liqui-Nox or equivalent) and clean the area of the spill.
3. Moisten a gauze sponge with a **10% solution of household bleach** and disinfect the area of the spill.
4. The 10% bleach solution should be allowed to react with the spilled material for a minimum of 10 minutes.
5. Absorb the bleach solution with a gauze sponge. Due to the corrosive nature of bleach, wipe the area with a gauze sponge moistened with water.

# Appendix C Installing Optional External Hardware

## External Printer

### Materials Required

You need the following items not supplied by bioMérieux Vitek:

- Epson compatible printer
- PC compatible printer cable, having a DB 25-pin connector on one end and a 36-pin Centronix connector on the other end.
- Small, flathead screwdriver

### Before Installation

Prior to installing the printer, make sure that the mini VIDAS has been configured to use an external printer.

Look in the mini VIDAS Table of Contents and locate the procedure in Chapter 2 titled Selecting the Printer. Perform this procedure, selecting the external printer option.

### Installing the External Printer

Step 1 Turn power to the mini VIDAS off.

Step 2 Set the printer near the mini VIDAS within reach of the printer cable and an appropriate electrical outlet.

Step 3

Locate the Printer Port on the rear of the mini VIDAS. The arrow in the figure below indicates its location.

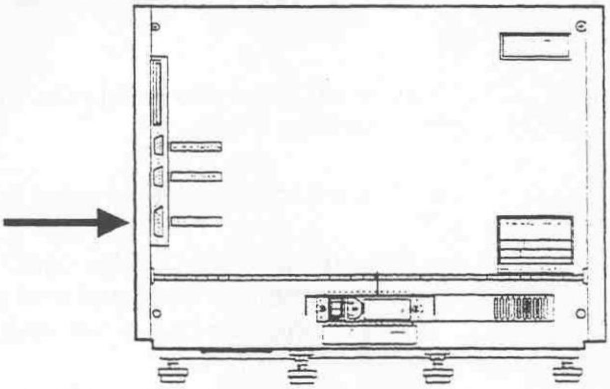


Figure C–1 Location of Printer Port

Step 4

Insert the DB 25-pin connector of the cable into the printer port.

The port and connector are shaped such that the cable can be successfully inserted in only one orientation.

Step 5

With the screwdriver, tighten the connector to the port.

Step 6

Insert the 36-pin Centronix connector into the port on the printer.

The port and connector are shaped such that the cable can be successfully inserted in only one orientation.

Step 7

Load the printer with paper per the manufacturer's instructions.

Step 8

Turn the printer on.

Step 9

Perform the procedure Starting the mini VIDAS, located in Chapter 2 of this manual.

## Testing the External Printer

Look in the mini VIDAS Table of Contents and locate the procedure in Chapter 6 titled Testing the Printer. Perform this procedure.

The external procedure should print the following test pattern:

```
ABCDEFGHIJKLMNOPQRSTUVWXYZ
abcdefghijklmnopqrstuvwxyz
```

## Bar Code Wand

**Materials Required**

You need the following items not supplied by bioMérieux Vitek:

A bar code wand. The following are those currently compatible with the mini VIDAS:

- HP SmartWand
- ZE-84 Wand (Panasonic)

**Before Installation**

Prior to installing the bar code wand, make sure that the mini VIDAS has been configured to use the correct wand.

Look in the mini VIDAS Table of Contents and locate the procedure in Chapter 2 titled Selecting a Bar Code Reader Wand. Perform this procedure, selecting the wand you have obtained.

### Installing the Bar Code Wand

Step 1

Turn power to the mini VIDAS off.

Step 2

Locate the Diagnostic Port on the rear of the mini VIDAS. The arrow in the following figure indicates its location.

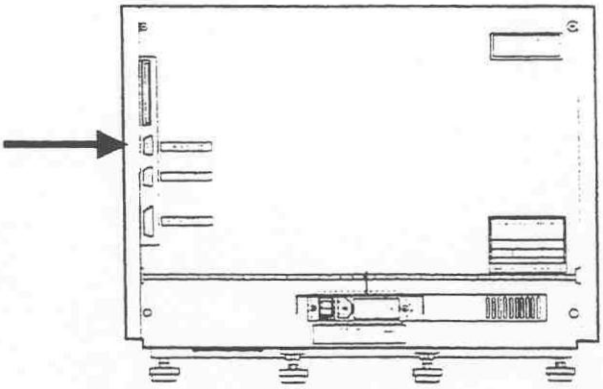


Figure C–2 Location of Diagnostic Port

Step 2

Connect the bar code wand cable to the diagnostic port.

The port and connector are shaped such that the cable can be successfully inserted in only one orientation.

Step 3

Perform the procedure Starting the mini VIDAS, located in Chapter 2 of this manual.

The bar code wand is now ready to use.

# Appendix D Computer Interface Information

## INTRODUCTION

bioMérieux Vitek, Inc. manufactures several different instruments which include the VITEK, VITEK Junior, VIDAS-30 and miniVIDAS. There are several different documents pertaining to the computer interface specifics for these different types of instruments.

The miniVIDAS is a standalone instrument that does not use a separate computer. The Vitek and VIDAS-30 use either a bioMérieux Vitek supplied Nerve Center or CC1 computer. This is not required for the miniVIDAS. Those miniVIDAS instruments at version VIC-2.1 software contain all that is necessary to support a literal unidirectional computer interface. This interface allows the miniVIDAS results to be transmitted (i.e., uploaded) to the Laboratory Information System (LIS) or other host computer system.

The same communications protocol that is used by the VIDAS-30 model is also used by the miniVIDAS, with one exception. The serial communications parameter number of stop bits is fixed at one (1). This protocol is described in detail in the bioMérieux Interface Products Specification (Part # 510649-3). This particular document should be referred to for further information in this area.

**Please Note the Following**

- The miniVIDAS interface does not require the presence of a bioMérieux Nerve Center or CC1 computer, as mentioned earlier. The miniVIDAS at version VIC- 2.1 software contains the necessary software and hardware for the interface.
- Cable Specifications: Follows the NCII DB9 layout as described in the Communications Section of the Interface Product Specification (#510649-3).
- The Download Section of the Interface Products Specification (#510649-3) mentioned above does not apply to the miniVIDAS. The miniVIDAS transmits only to the host computer (i.e., uploads test results).

- Section 3.1 - Field Types in the Upload Section of the Interface Products Specification (#510649-3) mentioned above lists those fields that are transmitted to the host computer (under the column VID).

  The pn and pi fields (patient name and patient identification) are not transmitted as part of the upload on a miniVIDAS. (They are included on the VIDAS-30.)

- All fields are transmitted for the miniVIDAS each time. There is not a TRANSMIT/SUPPRESS screen available as with the Vitek interface. This is not needed for the miniVIDAS as the number of transmitted fields is relatively few.

  The miniVIDAS fields that are transmitted include :

  | | |
  |---|---|
  | – mt | message type |
  | – pi | patient ID |
  | – pn | patient name |
  | – si | specimen separator |
  | – ci | sample ID |
  | – rt | short assay name |
  | – rn | long assay name |
  | – ql | qualitative result |
  | – qn | quantitative result |
  | – tt | test completion time |
  | – td | test completion date |
  | – qd | dilution (optional) |

  (See the Upload Section of the Interface Products Specification (#510649-3) for further information if needed.)

- A list of the miniVIDAS assays can be obtained directly from the miniVIDAS instrument.

  Select Utilities from the screen, then Miscellaneous Functions. From there, select Version Menu, then Print Assay Version. This will provide a printout of the available assays if needed.

- To verify the software version on a particular miniVIDAS instrument, select Utilities and Miscellaneous Functions. From there, select Version Menu and then Show Software Version to obtain the current version of software on that particular instrument.

- Results that are not uploaded :
  - Strips without a sample ID
  - QCT assay
  - FTI report
  - any raw result analysis type assays
- If attempts to upload results are unsuccessful, once the retry interval and number of retries (as specified in the LIS Interface Options) have elapsed, an error will be logged. You can view this log by selecting the ? on the keypad or view saved errors from the Utility menu selection.
- miniVIDAS results are not permanently stored in the instrument. Uploads should be performed on a routine basis.

## Configuration Information

Please note that the number of stop bits is fixed at one (1) for the miniVIDAS. From the Utility Menu, select the Configuration Menu option and then select LIS Interface Options to get to the options.

**A. LIS User Options** : (Enable the interface here)

<table>
<tr><th>B. LIS Interface Options:</th><th>Minim.</th><th>Maxim.</th><th>Default</th></tr>
<tr><td>• Communications Settings</td><td></td><td></td><td></td></tr>
<tr><td>Baud Rate</td><td>150</td><td>38400</td><td>1200</td></tr>
<tr><td>Parity ( none, odd, even, low, high )</td><td></td><td></td><td>none</td></tr>
<tr><td>Character Size</td><td>7</td><td>8</td><td>8</td></tr>
<tr><td>• Time Outs & Limits</td><td></td><td></td><td></td></tr>
<tr><td>Time Out</td><td>0</td><td>99</td><td>3</td></tr>
<tr><td>Checksum Retry Limit</td><td>0</td><td>99</td><td>3</td></tr>
<tr><td>Checksum Error Retry Interval</td><td>0</td><td>99</td><td>10</td></tr>
<tr><td><ENQ> Retry Limit</td><td>0</td><td>99</td><td>3</td></tr>
<tr><td><ENQ> Retry Interval</td><td>0</td><td>99</td><td>10</td></tr>
<tr><td>InterRecord Delay</td><td>0</td><td>99</td><td>0</td></tr>
<tr><td>InterMessage Delay</td><td>0</td><td>99</td><td>2</td></tr>
<tr><td>• Data Format</td><td></td><td></td><td></td></tr>
<tr><td>Miscellaneous Format</td><td colspan="2">(Alternate Protocol,<br>STX: <CR><LF><br>ETX: <CR><LF><br>RS: <CR><LF><br>GS: <CR><LF><br>ENQ: <CR><LF><br>EOT: <CR><LF><br>Send Dilution (option))</td><td></td></tr>
<tr><td>Time Separators</td><td colspan="2">. : / - ,</td><td>:</td></tr>
<tr><td>Date Separators</td><td colspan="2">. : / - ,</td><td>/</td></tr>
<tr><td>Field Terminators</td><td colspan="2">! @ # $ % ^ & * ( ) -<br>= + < > / ? [ ] \ | { }</td><td>|</td></tr>
<tr><td>• Send Test Message</td><td colspan="2">(Use to send a test pattern message.)</td><td></td></tr>
</table>

## EXAMPLE of a miniVIDAS Upload

```
mtrsl |

    si |

    ci218421 |

    rtRSV | rnRespiratory Syncytial Virus | qlNegative | qn< 0.40 ug/ml |
```

# Glossary

| | |
|---|---|
| **Assay** | A complete test procedure using immunological methods and fluorescent chemistry to detect or quantify an analyte. |
| **Assay analysis** | Interpretation of data using sample assay data, standard assay data, and thresholds for data comparison. These calculations can be different for each type of assay and can interpret the assay result. |
| **Assay code** | A two-, three-, or four-character designation for an assay used in the mini VIDAS. Assays are defined in the system, for example, using the assay code. |
| **Assay Compatibility** | The property that two or more assay type have when they utilize the same protocol in the mini VIDAS. |
| **Assay kit** | A package containing a set of Reagent Strips, SPRs, and a package insert along with any necessary controls, standards, and sample treatment reagents. |
| **Background** | The native fluorescence that a sample has without the intended chemical reaction for the assay. |
| **BAP card** | The Barcode Assay and Protocol, or BAP card, contains information about a particular assay and the protocol used to run it. This information, contained within bar codes printed on the card, updates the mini VIDAS software to enable it to run the new assay. |
| **Bar code** | A series of lines printed on the label of a Reagent Strip. The encoded information can be read and interpreted by the scanner and used to identify the strip. |
| **Calibration** | The process of adjusting the standard curve of a quantitative assay lot. |
| **Calibration curve** | A set of data, supplied by bioMérieux Vitek with each lot of a quantitative assay, that becomes the standard curve for that lot. |
| **Central processing unit** | The portion of a computer that is responsible for processing software instructions. |

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|---|---|
| **Cuvette** | The last of the 10 wells of the Reagent Strip. It is made of optically clear plastic that permits the scanner to take an accurate fluorometric reading of the substrate. |
| **Defined run** | An assay run in which assay types, sample IDs, standards, and controls are defined on the mini VIDAS prior to the start of the run. |
| **Dual Reagent Strip** | A strip consisting of a jointly attached sample reference Reagent Strip (left) and a sample test Reagent Strip (right). |
| **Equivocal** | An assay analysis result that is neither positive/reactive nor negative/nonreactive; it falls between the high and low threshold values for the test. |
| **Fluorescence** | A physical process in which a substance, after exposure to light at a specific wavelength, emits light at another wavelength. This is the process used for analyte detection in the mini VIDAS. |
| **Fluorescent units** | A numerical value that represents the intensity of fluorescence detected by the optical scanner. |
| **Load and Go run** | An assay run in which reagent strips are placed into the mini VIDAS and run without any prior definition on the system. |
| **Master lot data** | A set of data, supplied by bioMérieux Vitek with each lot of an assay that supplies quality control ranges and, for quantitative assays, becomes the standard curve for that lot. |
| **MLE card** | The Master Lot Entry, or MLE card, is used to enter master lot data into the mini VIDAS. The card is printed with bar coded data that is read on a Section of the instrument. |
| **Online help** | A screen display of a mini VIDAS data directory that can be activated during the execution of another program. |
| **Optical cuvette** | The last of the ten wells of the Reagent Strip. It is made of optically clear plastic that permits the scanner to take an accurate fluorometric reading of the substrate. |
| **Optical scanner** | A component of the mini VIDAS that reads the bar code label and measures the intensity of fluorescence of the assay. |

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|---|---|
| **Paging** | The process of displaying additional or previous information in a directory that does not fit on one display screen. |
| **Port** | A cable connection site on the back of the mini VIDAS. |
| **Position** | The Reagent Strip and SPR slots in the mini VIDAS where a Reagent Strip/SPR pair can be placed. |
| **Protocol** | A specific sequence of computer-controlled activities (pipetting, mixing, incubating, reading, etc.) needed to perform an assay. Only assays with identical Protocols can be run in the same Section. |
| **Reagent Strip** | A polypropylene strip of 10 wells with a foil seal and paper label. The first well at the handle end of the strip is for the sample. The next eight wells contain the various reagents required for the immunoassay. The last well of the strip is the optically clear cuvette that contains the substrate. |
| **Reagent Strip compartment** | A temperature-controlled tray with a plastic cover containing six Section channels that hold six Reagent Strips or three Dual Reagent Strips. |
| **Reagent Strip tray** | The temperature-controlled tray within the Reagent Strip compartment. Also called Section Tray. |
| **Reference strip** | The Reagent Strip in a dual strip pair that is used to measure the background reading for the sample. |
| **Relative Fluorescence Value (RFV)** | The difference between the final and the initial (background) fluorescent readings of a Reagent Strip. |
| **Replicates** | The multiple samples of a standard that are run, and of which an average value is calculated. |
| **Result** | The qualitative interpretation of the Test Value. Possible Result values are "Positive," "Negative," or "Equivocal." |
| **Sample** | The patient material being tested. |
| **Scanner** | A unit in the mini VIDAS that contains the fluorescent detector and the bar code reader. |

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| **Section** | A microprocessor-controlled assay processing unit in the mini VIDAS instrument. Each instrument has two Sections. Each Section contains a SPR compartment with six corresponding Reagent Strip channels. A SPR position and its corresponding Reagent Strip channel make one test Position. |
| **Section channel** | A groove in a Section tray that holds a Reagent Strip. Channels are designated one through six. Each has a corresponding SPR position in the SPR compartment. |
| **Section tray** | A temperature-controlled plate with six channels to hold six Single Reagent Strips or three Dual Reagent Strips. Also called Reagent Strip tray. |
| **Single Reagent Strip.** | See Reagent Strip. |
| **Solid Phase Receptacle (SPR)** | A specially designed plastic pipette-shaped device with its inside wall coated with antibody, antigen, or other treatments that allow capture of a target analyte. Each SPR has a corresponding mini VIDAS Reagent Strip. |
| **SPR compartment** | A temperature-controlled block with receptacles to hold six SPRs. Each has a Position for a corresponding Reagent Strip immediately below it in the section. A tilt-down door provides access to the SPR compartment. |
| **Standard** | A solution containing a known analyte concentration. The RFV obtained from testing a Standard is used to interpret the test values of the patient samples and controls. |
| **Stored Standard** | The test result of a standard, stored as data in the mini VIDAS system, and used to calculate results for test samples over a period of time. |
| **Substrate** | A substance in the Reagent Strip that is broken down enzymatically to create a compound that fluoresces. |
| **Test** | That portion of an assay kit used to process a specimen, control, or standard; consists of a paired Reagent Strip and SPR(s). |
| **Test value** | The result calculated using the Relative Fluorescent Value (RFV) of the sample and the Relative Fluorescent Value of the reference or of the standard, depending upon whether it is a Dual or Single Reagent Strip, respectively. |

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|---|---|
| **Threshold** | A numerical value used to translate the Test Value to qualitative results such as positive. |
| **TOS sheet** | A sheet of paper printed with bar coded master lot data. The data is read into the mini VIDAS using a hand-held bar code scanner. |

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